Attachment 2

Request from the California Society of Health-System Pharmacists to amend 16 CCR section 1793.7 and 1793.8, to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes

Blank

SUBMITTED BY CSHP

PROPOSED AMENDMENTS & ADDITION
TITLE 16 CCR SECTION 1793.7 & 1793.8

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) ~~a.~~ Any pharmacy which employs a pharmacy technician shall do so in compliance with applicable federal and state laws and regulations governing pharmacy.

(b) ~~b.~~ Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(c) ~~c.~~ Pharmacy technicians must work under the direct supervision of a registered pharmacist and in such a relationship that the supervising pharmacist is on the premises at all times and is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, a pharmacy technician may perform the duties, as specified in subdivision 1793.2, only under the immediate, personal supervision and control of a registered pharmacist and within the pharmacist's view.

(d) ~~d.~~ A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(e) ~~e.~~ Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 12 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(f) ~~f. Except as otherwise provided herein, the ratio of pharmacists to pharmacy technicians performing the duties specified in subsection 1793.2 shall not be less than one pharmacist on duty for each pharmacy technician on duty.~~ For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), these ratios shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4115 Business and Professions Code.
Reference cited: Sections 4007 and 4115 Business and Professions Code.

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) Notwithstanding any other provision of law, general acute care hospitals, as defined in Health and Safety Code 1250 (a), that have an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist in charge;

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures;

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility;

(4) To ensure quality, there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Authority cited: Sections 4005, 4115, Business and Professions Code.
Reference cited: Sections 4007 and 4115, Business and Professions Code.

REGULATION ANALYSIS

AMEND CCR 1793.7 ADD CCR 1793.8 **January 19, 2006**

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

SPONSOR: CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS (CSHP)

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Regulation:

1) Amends CCR 1793.7 to allow pharmacy technicians to check the work of other pharmacy technicians (TCT) in accordance with CCR 1793.8. (CCR 1793.7 Amended)

2) Permits general acute care hospitals that have an ongoing clinical pharmacy program to use TCT in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

3) Requires compounded or repackaged products to be checked by a pharmacist prior to a technician filling unit dose distribution systems, and floor and ward stock.

4) Requires TCT programs to include the following components:

a. The overall operation of the program shall be the responsibility of the pharmacist in charge;
b. The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures;

c. The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility;

d. To ensure quality, there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

(CCR 1793.8 Added)

Comment:

1) Sponsor's Intent. For over ten years the California Society of Health-System Pharmacists (CSHP) has supported both regulation and legislative attempts that would permit TCT programs. Most recently CSPH sponsored SB 393 (2003) and SB 592 (2005) to permit TCT. Both bills met with opposition from labor and failed to make it out of the Assembly.

2) Board Authority. In 1995, the board initiated a rulemaking process for TCT. At the time some questioned whether the board had the authority to promulgate TCT regulations. Bion Gregory, Legislative Counsel, determined the board has the authority to promulgate TCT regulations.

3) Accuracy and Usefulness of TCT. Two studies have been conducted by Long Beach Memorial Medical Center, Cedar-Sinai Medical Center, and the UCSF School or Pharmacy to determine the accuracy and usefulness of TCT.

The first study, "Evaluating the Accuracy of Technicians and Pharmacists in Checking Unit Dose Medication Cassettes" was conducted from 1998-2000. The study determined that certified technicians had an accuracy rate of 99.88% compared with pharmacists who had an accuracy rate of 99.52% for checking unit-dose cassettes.

The second study, will evaluate the impact of pharmacists in preventing medication errors associated with prescribing and administering medications as a result of pharmacists being re-deployed form unit-dose medication cassette checking to clinical and professional functions. The study began in 2004 and will be completed in 2006.

Interim results presented at the board's July 2005 meeting, show that redeploying a pharmacist for 1.5 hours a day over 48 weeks resulted in pharmacists intercepting 1,296 medication errors, and allowed 27,450 medication related encounters including the dosing of medications per doctors' requests, participation in codes, and rounds and drug information questions. Overall these interceptions prevented temporary harm to 387 patients, permanent harm to 11 patients, and one death. Results from the complete study will be presented to the board in late summer or fall of 2006.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 592 | **VERSION: AMENDED MARCH 29, 2005**

AUTHOR: AANESTEAD | **SPONSOR: CALIFORNIA SOCIETY OF HEALTH SYSTEMS PHARMACISTS**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128 Added)

2) Requires hospitals implementing TCT to do the following:

a. Conduct ongoing training for technicians.
b. Conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. Remove any technician in TCT programs whose accuracy rate falls below 99.8 percent.

d. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), or another nationally recognized accrediting organization.

e. Be inspected by the Board of Pharmacy.

f. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

3) Requires training for pharmacy technicians to include both didactic and practical elements, and to be completed prior to technicians commencing participation in the checking program.

a. The didactic component of the training shall consist of at least four hours of education covering the following topics:
   i. Information required to be on the label of unit dose or extemporaneous packaging.
   ii. Identification of expired or contaminated medications.
   iii. The product characteristics that need to be checked for each drug dispensed from the pharmacy.
   iv. Special packaging or handling requirements, including refrigeration for certain medications.
   v. Generic names for common name-brand medications.
   vi. Recognition and identification of various dosage forms.
   vii. Common medical abbreviations and symbols used in pharmacy.
   viii. Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

b. The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(B&P 4128 Added)

4) Permits the board to adopt other rules related to TCT. (B&P 4128 Added)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128 Added)

6) Requires that data and records for TCT programs be retained for three years.

(B&P 4128 Added)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128 Added)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1Added)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1 Added)

<u>Comment:</u>

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Legislative History. In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Workers Union. The measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

3) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the April 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in April 2006.

4) Amended on March 29, 2005. The amendments 1) detail training for pharmacy technicians who participate in the program, and 2) specified requirements for the quality improvement program required by the measurer. This version of the bill is similar to AB 393, as amended on July 16, 2003.

5) History.

2005	
June 14	Set, first hearing. Failed passage in committee. Reconsideration granted.
May 26	To Com. on HEALTH.
May 9	In Assembly. Read first time. Held at Desk.
May 9	Read third time. Passed. (Ayes 23. Noes 8. Page 972.) To Assembly.
May 3	Read second time. To third reading.
May 2	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 21	Set for hearing May 2.
Apr. 18	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 4. Noes 1. Page 625.) Re-referred to Com. on APPR.
Mar. 30	Set for hearing April 18.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Blank

Board History: Technicians Checking Technicians (TCT) 1995 to 2006

July 1993	Board Meeting – Board appoints a committee to research hospital practices with regards to the possible use of TCT. The committee recommended that the board adopt proposed regulations.
May 1995	Board Meeting – Board members discuss pharmacy technicians' duties and their concern that some employees may be asking techs to perform illegal activities. It was estimated that 50% of all hospitals in Southern California use TCT.
July 1995	Board Meeting - Board members discuss TCT. Washington and Minnesota allow TCT. In 1995 California law did not require hospital techs to be licensed. California Society of Health-System Pharmacists (CSHP) supports TCT, the California Pharmacist Association (CPhA) opposes TCT. There is general agreement among the board members that hospital techs should be licensed if TCT moves forward. The board approves a motion to notice CCR 1793.8.
October 1995	Regulation Hearing to amend CCR 1793.7 and adopt 1793.8. The regulation would establish requirements for a class of pharmacy tech authorized to participate in TCT. Discussion. Does the Board have the authority to adopt this regulation? Staff Counsel Chris Grossgart stated that the board has the authority. Board votes to reject the regulation and refers this issue to the board's Pharmacy Technician Committee.
July 1996	Pharmacy Technician Committee – Brief discussion on TCT. One proposal would be to require hospitals to apply to the board to have a TCT program and impose reporting requirements to the board to evaluate effectiveness. Also discussed was SB 1553 (1996) which would require the registration of techs working for hospitals and correction facilities.
January 1997	Board Meeting – Board members approve a motion to pursue a regulation authorizing a waiver program for techs to be able to check the filling of unit dose cassettes in an inpatient setting.
May 2, 1997	Notice published for to amend CCR 1793.7 and adopt 1793.8 to allow hospitals to apply for a waiver to allow techs to be able to check the filling of unit dose cassettes in an inpatient setting. Comment period ends June 16, 1997.
May 1997	Board Meeting - Board members discuss proposed TCT regulation. The board approves a motion to cancel the regulation hearing scheduled for July 1997, and moves the technician issue to the board's Licensing Committee.
May 1998	Board Meeting - Long Beach Memorial Medical Center, Cedar-Sinai Medical Center, and the UCSF School or Pharmacy request a waiver from CCR 1731 to conduct a two-year study to evaluate TCT. Waiver granted until November 2000.
October 2000	Board Meeting – UCSF request a waiver to continue TCT study until February 1, 2001. Board grants waiver.

January 2001	Board Meeting - Dr. Peter Ambrose, UCSF, presented results of the study. <u>Pharmacist</u> checking unit-dose cassettes had an <u>accuracy rate of 99.52%</u> compared with **99.88% for certified technicians** performing the same task. The board approves a motion to move forward with legislation or regulation to allow TCT. The Board approves a motion to extend UCSF's waiver until the end of the 2002 Legislative Session (December 2002) to allow for passage of legislation or regulation.
June 2002	The results of UCSF's TCT study are published in the June 15, 2002 issue of the American Journal of Health-System Pharmacists.
October 2002	Board Meeting - UCSF request and the board grants a continuation of UCSF's waiver until December 2004. CSHP will sponsor legislation in January 2003 to allow TCT.
April 2003	Board Meeting – Board approves a position of Support if Amended on SB 393 (Aanestead 2003) TCT. The amendment would delete the requirement for the board approve regulations in association with TCT and instead place the criteria directly into the law. Note: SB 393 died in the Senate.
January 2004	Board Meeting - Dr. Peter Ambrose, UCSF, presented the final results of the UCSF study that ended in December 2003. He states that no medication errors were reported as a result of TCT. The board asked the Licensing Committee to review the issue of TCT and report back to the board.
April 2004	Board Meeting - Dr. Peter Ambrose, UCSF, request a two year waiver for TCT to evaluate the impact of pharmacists in preventing medication errors associated with prescribing and administering medications as a result of pharmacists being re-deployed form unit-dose medication cassette checking to clinical and professional functions. The Board approves a two-year waiver with the understanding that an interim report will be provided after one year.
February 2005	SB 592 (Aanestead) TCT introduced, based on SB 393 (Aanestead 2003) TCT. SB 592 is currently in the Assembly Health Committee and is likely to die in the Assembly on January 31, 2006. The board has a position of support on the measure.
July 2005	Board Meeting - Dr. Rita Shane, Director of Pharmacy Services, Cedar-Sinai Medical Center, presented interim results of his latest study. The results demonstrate that having specially trained pharmacy techs performing the non-discretionary task of checking technician filled unit-dose medication carts frees up time for pharmacists to play a role in intercepting potential medication errors and preventing harm to patients.
October 2005	Legislation Committee Hearing - Maria Serpa, CSHP representative, presented proposed language for TCT. Committee directs staff to compare the regulation with SB 592 (2005) and report back to the committee.

STATE OF CALIFORNIA

Memorandum

To: PATRICIA F. HARRIS
Executive Officer
Board of Pharmacy

Date: October 13, 1994

Telephone: (916) 445-4216
ATSS: 8-485-4216
FAX: (916) 323-0971

From: **Department of Consumer Affairs**
Legal Office

Subject: Direct Supervision of Pharmacy Technicians

I. BACKGROUND.

As you are aware, the Hospital Pharmacy Committee is proposing regulations ("the Proposed Regulations") which would allow pharmacy technicians employed in inpatient hospitals, skilled nursing facilities and correctional facilities (referred to collectively as "Inpatient Pharmacy Technicians" or "IPTs") to "check" certain tasks performed by other IPTs. Specifically, the Committee proposes to authorize IPTs to check unit dose cassettes and floor and ward stocks filled by other IPTs. An IPT would perform this "check" in lieu of the supervising pharmacist.

You asked whether the Proposed Regulations would be inconsistent with, and thus precluded by, existing statute which requires IPTs to work under the "direct supervision and control" of pharmacists.

Subject to the discussion below, I conclude that, although existing statute requires the supervising pharmacist to be present in the facility at the time the IPT is performing his or her duties, the pharmacist is not required to personally check unit dose cassettes and floor and ward stocks filled by an IPT. Instead, the pharmacist may authorize another IPT to perform such checks.

II. DISCUSSION.

The functions performed by pharmacy technicians, and the supervision required in the performance of those functions, are governed by Business and Professions Code Section 4008.5 and regulations promulgated under that statute.[1] Subdivision (b) of Section 4008.5 requires IPTs to work under the direct supervision and control of pharmacists. It provides:

> (b) Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, and other nondiscretionary tasks, while assisting, and under the direct supervision and control of, a registered pharmacist. (Emphasis added.)[2]

Under Section 4008.5, an IPT may fill unit dose cassettes and floor stocks under a pharmacist's direct supervision and control. As indicated, the Proposed Regulations would authorize a pharmacist to delegate the responsibility of checking the filled cassettes and floor stock to another IPT. The Pharmacy Board may not adopt the Proposed Regulations without statutory amendment if the "direct supervision and control" standard requires the supervising pharmacist to personally check such tasks. In order to resolve this question, we must determine what is required under "direct supervision and control".

The term "direct supervision and control" is not defined in the Pharmacy Law. Nor has any court defined this term for purposes of Section 4008.5. Therefore, I have looked to other

---

[1]Unless otherwise specifically stated, all references herein are to the Business and Professions Code.

[2]Note that Section 4008.5 creates two levels, or standards, of supervision. Subdivision (f)(2) creates a second standard which is more stringent than that set forth in Subdivision (b). It provides, in relevant part:

> . . . A pharmacy technician may perform the duties, as specified in subdivision (b) only under the immediate, personal supervision and control of, a registered pharmacist. (Emphasis added.)

This second standard, "immediate, personal supervision and control", does not apply to pharmacy technicians who are employed in inpatient hospitals or correctional facilities. (See § 4008.5(f)(5).) Hence, the first standard of supervision, namely "direct supervision and control", is applicable to IPTs.

statutes in the Business and Professions Code for guidance. Although the term "direct supervision and control" does not appear in other practice acts, the term "direct supervision" is used several times.[3]

Under other practice acts, the terms "direct supervision" means that the supervisor must be present in the facility at the time the supervised trainee or employee is performing duties which require supervision. I have found no statutes in the Business and Professions Code which define "direct supervision" to require the supervisor to personally check all tasks completed by supervised employees.

For example, under the Dental Practice Act, dental auxiliaries are required to perform many of their duties under the direct supervision of a dentist. "Direct supervision" under the Dental Practice Act is defined as:

> supervision of dental procedures based on instructions given by a licensed dentist, <u>who must be physically present in the treatment facility during the performance of those procedures</u>. (<u>Emphasis added</u>; B&P Code § 1741.)

Thus, Section 1741 provides only that the supervising dentist must be present in the treatment facility at the time the auxiliary is performing assigned tasks. The statute does not require the dentist to personally review an auxiliary's work product.

Similarly, under the Medical Practice Act, student and intern perfusionists must work under the direct supervision of a perfusionist who has met certain statutory requirements. (B&P Code § 2593.) For purposes of section 2593, "direct supervision" means that the supervising perfusionist is on duty and

---

[3]Other practice acts are not binding on the Pharmacy Board. However, a review of other statutes in the Business and Professions Code which define the term "direct supervision" may aid us in determining legislative intent behind Section 4408.5.

immediately available in the assigned patient care area. Again, the supervising perfusionist is not required to personally check all tasks completed by students and interns under his or her supervision.

Also under the Medical Practice Act, student respiratory care practitioners are required to work under direct supervision. Section 3742 provides:

> During the period of any clinical training, a student respiratory care practitioner shall be under the direct supervision of a person holding a valid and current license issued under this chapter. "Under the direct supervision" means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area. (Emphasis added.)

The fact that the Legislature, in regulating other health professions, has not defined "direct supervision" to require licensees to personally check the work of employees under their supervision, suggests that the Legislature did not intend to impose such requirements under the Pharmacy Law.

Moreover, had the Legislature intended to require Pharmacists to personally check the work product of IPTs, it would have expressly so stated. As we have seen, community pharmacy technicians must work under the immediate, personal supervision and control of a pharmacist. Although this term is not defined, the words "immediate" and "personal" suggest that there is no intermediate supervision between the supervisior and the pharmacy technician. Also, logic dictates that in the community pharmacy setting, where drugs are supplied directly to the consumer rather than to an intermediary medical professional, the pharmacist must closely scrutinize, and presumably personally check, the work of pharmacy technicians. Had the Legislature intended to impose similar requirements on IPTs, it would not have exempted IPTs from the standard of "immediate, personal supervision and control".

III. CONCLUSION.

Based on the preceding discussion, I conclude that the Proposed Regulations, which would authorize a pharmacist in an inpatient hospital, skilled nursing facility or correctional institution to delegate to a pharmacy technician the task of "checking" unit dose cassettes and ward stocks filled by another pharmacy technician, is consistent with Section 4008.5.

DERRY L. KNIGHT
Deputy Director
Legal Affairs

Chris Grossgart

By CHRISTOPHER GROSSGART
Staff Counsel

CG:slb

Blank

State Capitol, Suite 3021
Sacramento, CA 95814-4996
(916) 445-3057
Telecopier: (916) 322-0769

Legislative Counsel of California

BION M. GREGORY

Sacramento, California
August 24, 1995

Honorable Thomas M. Hannigan
3104 State Capitol

<u>Pharmacy Technicians - #28213</u>

Dear Mr. Hannigan:

QUESTION

May a regulation be adopted by the California State Board of Pharmacy pursuant to Section 4008.5 of the Business and Professions Code to allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians?

OPINION

A regulation may be adopted by the California State Board of Pharmacy pursuant to Section 4008.5 of the Business and Professions Code to allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians.

ANALYSIS

The Pharmacy Law, contained in Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code,[1] provides for the licensing and regulation of pharmacies and pharmacists (Sec. 4049.6). It sets forth registration and other regulatory requirements for pharmacy technicians, describes the

[1] All further section references are to the Business and Professions Code.

functions that they may perform including the required level of supervision, and requires the California State Board of Pharmacy (hereafter the board) to adopt regulations specifying these tasks (Secs. 4008 and 4008.5).

Section 4008.5 provides as follows:

> "4008.5. (a) As used in this section "pharmacy technician" means an individual who assists a registered pharmacist in a pharmacy in the performance of his or her pharmacy related duties as specified in subdivision (b).
>
> "(b) Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and <u>while under the direct supervision and control of, a registered pharmacist</u>.
>
> "(c) This section does not authorize the performance of any tasks specified in subdivision (b) by a pharmacy technician without a registered pharmacist on duty, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (b) except under the direct supervision and control of a registered pharmacist.
>
> "(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a registered pharmacist.
>
> "(e) The board shall adopt regulations to specify tasks pursuant to subdivision (b) which a pharmacy technician may perform under the direct supervision and control of a registered pharmacist. Any pharmacy that employs a pharmacy technician to perform tasks specified in subdivision (b) shall do so in conformity with the regulations adopted by the board pursuant to this subdivision.
>
> "(f) (1) No person shall act as a pharmacy technician without first being registered with the board as a pharmacy technician. The board shall issue a certificate to an applicant who has met any of the following requirements:

"(A) Has obtained an Associate of Arts degree in a field of study directly related to the duties performed by a pharmacy technician.

"(B) Has completed a course of training specified by the board.

"(C) Is eligible to take the board's pharmacist licensure examination.

"(D) Has provided satisfactory proof to the board of one year's experience performing the tasks specified in subdivision (b) while employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital, for an inmate of a correctional facility, or experience deemed equivalent by the board.

"(2) The performance of duties by a registered pharmacy technician shall be under the direct supervision and control of a registered pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (b) only under the immediate, personal supervision and control of, a registered pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

"(3) The board shall adopt regulations pursuant to this section for the registration of pharmacy technicians. Proof of the qualifications of any applicant for registration as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by evidence as may be required by the board.

"The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts which would constitute grounds for denial of registration, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5. The board may suspend or revoke any registration issued pursuant to this section on any ground specified in Section 4350.5.

"(4) The board shall adopt regulations pursuant to this subdivision for the specification of training courses for pharmacy technicians.

"(5) Paragraphs (1) to (4), inclusive, of this subdivision shall not apply to persons employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.

"(g) (1) The ratio of pharmacy technicians performing the tasks specified in subdivision (b) to registered pharmacists shall not exceed one to one, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4008.4. This ratio is applicable to all practice settings except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

"(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (b) to registered pharmacists applicable to the filling of prescriptions for an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for each pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4008.4." (Emphasis added.)

"Inpatient pharmacy technician" as used in Section 4008.5 refers to pharmacy technicians in inpatient hospital or correctional facility pharmacies that provide prescriptions for inpatients of the hospital or facility (see para. (5), subd. (f), Sec. 4008.5). Subdivision (f) of Section 4008.5 establishes additional requirements, including enhanced supervision requirements, applicable only to pharmacy technicians in outpatient pharmacy settings (para. (5), subd. (f), Sec. 4008.5; see Californians for Safe Prescriptions v. California State Bd. of Pharmacy, 19 Cal. App. 4th 1136, 1154, fn. 4).

The term "direct supervision and control" is not defined for the purposes of Section 4008.5. We think that the term is amenable to at least two possible constructions.

"Direct supervision and control" could include the use of inpatient pharmacy technicians under the supervision of the registered pharmacist to check certain tasks performed by other inpatient pharmacy technicians. When used in similar provisions relating to other health professions, "direct supervision" is usually defined to mean that the licensed or registered professional is on duty and physically present where the service or task is being performed (see Secs. 1741, 2593, and 3742).

In this regard, you have provided us with a written opinion of the Legal Office of the Department of Consumer Affairs (hereafter the department) to the Executive Officer of the Board of Pharmacy dated October 13, 1994, concluding that "... the Proposed Regulations, which would authorize a pharmacist in an inpatient hospital, skilled nursing facility or correctional institution to delegate to a pharmacy technician the task of 'checking' unit dose cassettes and ward stocks filled by another technician, is [sic] consistent with Section 4008.5."

The 1994 opinion of the Legal Office of the Department of Consumer Affairs noted that Section 4008.5 establishes two different supervision standards for supervision of pharmacy technicians based upon whether they are in an inpatient hospital or correctional facility, or in a community setting, and by analogy to provisions regulating other health professions, reasoned that "direct supervision and control" as used in the context of supervision of pharmacy technicians meant only that the registered pharmacist was required to be present on the premises during performance of the tasks in question by the pharmacy technicians.

That opinion stated, in part, as follows:

> "Moreover, had the Legislature intended to require Pharmacists to personally check the work product of IPTs [inpatient pharmacy technicians], it would have expressly so stated. As we have seen, community pharmacy technicians must work under the <u>immediate</u>, <u>personal</u> <u>supervision</u> <u>and</u> <u>control</u> of the pharmacist. Although this term is not defined, the words 'immediate' and 'personal' suggest that there is no intermediate supervision between the supervisor and the pharmacy technician. . . . Had the Legislature intended to impose similar requirements on IPTs, it would not have

exempted IPTs from the standard of immediate, personal supervision and control."

It could alternatively be argued that the department's construction fails to address whether the review by an inpatient pharmacy technician of the tasks by another constitutes "supervision" for purposes of Section 4008.5 and if so, whether the supervising registered pharmacist may use an intervening agent.

To ascertain the meaning of a statute, the language in which the statute is framed is the starting point (People v. Overstreet, 42 Cal. 3d 891, 895). Statutory terms should be construed in accordance with the usual or ordinary meaning of the words used (People ex rel. Younger v. Superior Court, 16 Cal. 3d 30, 43).

An ordinary meaning of "supervise" is "... to coordinate, direct, and inspect continuously and at first hand the accomplishment of ..." (Webster's Third New International Dictionary, p. 2296). Reviewing the performance of tasks performed by pharmacy technicians as a general rule could fall within this ordinary meaning of "supervise." Also, an ordinary meaning of "direct" is "... from the source or the original without interruption or diversion ... without any intervening agency or step: without any intruding or diverting factor ... without use of a broker or other middleman ..." (Webster's Third New International Dictionary, p. 640). Moreover, use of a pharmacy technician to conduct the review of other pharmacy technicians would make the reviewing technician an intervening agent or middleman, and would thus make the registered pharmacist's supervision indirect.

In this regard, supervision is required to be "direct" for both community and inpatient pharmacy technicians (subd. (b), and para. (2), subd. (f), Sec. 4008.5). Thus, the enhanced supervision requirement for community pharmacy technicians does not infer that intervening agents may be used in inpatient settings. A close reading of paragraph (2) of subdivision (f) indicates that the supervision in all cases must be "direct" and that the registered pharmacist must be present at the facility (subd. (b), and para. (2), subd. (f), Sec. 4008.5).

Further, the additional requirements that supervision be "immediate," "personal," and "within the pharmacist's view" in the case of a community pharmacy technician might indicate only that the pharmacist is to be more readily available, and that the supervision is to be more closely maintained. In other words, supervision is "direct" if no intervening agent is permitted between the pharmacist and the technician regardless of how closely the supervision is maintained. This is arguably the reason that the Legislature also required the presence of the registered pharmacist at the facility in all cases (subd. (c), and para. (2), subd. (f), Sec. 4008.5).

To additionally require that the supervision be "immediate," "personal," and "within the pharmacist's view" in community settings would not under this alternative construction alter the overall general requirement that the supervision be direct (para. (2), subd. (f), Sec. 4008.5). Since "immediate" is used in a context where the supervision is already required to be "direct," the Legislature arguably intended to require that the supervisor be close at hand. The ordinary meaning of the word "immediate" includes "... being near at hand: not far apart or distant" (Webster's Third New International Dictionary, p. 1129). This construction is consistent with the other community supervision enhancements that the supervision be "personal" and "within the pharmacists view."

Thus, the ordinary meaning of "direct supervision" under this alternative construction to that of the department would require that the registered pharmacist not utilize intervening agents in performing supervision in any setting including any review of the performance of pharmacy technicians working under his or her control.

Based on this alternative analysis, we are persuaded that the most reasonable construction of Section 4008.5 would prohibit a registered pharmacist from utilizing any agents for performance of supervision duties including the review of pharmacy technician performance of any tasks within the scope of subdivision (b) of Section 4008.5.

However, in the case of Californians for Safe Prescriptions v. California State Bd. of Pharmacy, supra, the court upheld related regulations of the board against various challenges, including the assertion that they conflicted with statutory authority. The court stated that "'[i]n determining whether a specific administrative rule falls within the coverage of a delegated power, our sole function is to decide whether the promulgating agency reasonably interpreted the legislative mandate. In doing so, we may not substitute our independent judgement for that of the administrative agency on the facts of or the policy considerations involved. Under this standard of review, we must determine whether the agency reasonably interpreted its legislative mandate when deciding that the challenged regulation was necessary to accomplish the purpose of the statute. Stated another way, our role is limited to determining whether the regulation is reasonably designed to aid a statutory objective.'" (Californians for Safe Prescriptions v. California State Bd. of Pharmacy, supra, at p. 1150, quoting from Benton v. Board of Supervisors, 226 Cal. App. 3d 1467, 1479).

The court in Californians for Safe Prescriptions v. California State Bd. of Pharmacy upheld regulations that permit pharmacy technicians to remove drugs from stock; count, pour, and mix pharmaceuticals; place drugs in containers; package and repackage drugs; and affix labels to containers (Californians for Safe Prescriptions v. California State Bd. of Pharmacy, supra, at p. 1149; 16 Cal. Code Regs. Sec. 1793.2). This regulation was adopted to implement subdivision (b) of Section 4008.5 authorizing a pharmacy technician to "perform packaging, manipulative, repetitive, or other nondiscretionary tasks." The court reasoned that the regulation was valid because it was consistent with "the legislative mandate allowing pharmacy technicians to perform nondiscretionary tasks while assisting, and while under the direct supervision and control of a registered pharmacist" (Id., at p. 1150).

We think, if the courts would allow sufficient discretion to the board to permit the counting, pouring, and mixing, of drugs by pharmacy technicians based upon subdivision (b) of Section 4008.5, a statute that does not expressly provide for performance of those tasks by pharmacy technicians, that the courts would apply the same rationale to also permit the board to allow inpatient pharmacy technicians to check tasks performed by other inpatient pharmacy technicians. This is, in part, because Section 4008.5 can reasonably be construed to permit a higher degree of independence and enhanced responsibilities for inpatient pharmacy technicians.

Also, you have informed us that the specific tasks to be checked by the inpatient pharmacy technician include the filling of unit dosage cassettes and the maintaining of floor and ward stocks. The board could reasonably conclude, for purposes of Section 4008.5, that maintenance of floor and ward stock are functions that do not require "direct supervision." In this regard, Section 4008.4 provides that the regulatory authority of the board does not include any regulation requiring the registered pharmacist to personally perform clerical, inventory control, housekeeping, maintenance, or similar functions for which the eduction, experience, training, and specialized knowledge of the registered pharmacist is not required, except that the regulations may require that these functions be performed under the "effective supervision" of the registered pharmacist (Sec. 4008.4).

Section 4008.4, thus, infers that the board is granted more flexibility in adopting regulations establishing the level of supervision for clerical and related tasks (Sec. 4008.4). To the extent, therefore, that maintaining floor and ward stock may be characterized as a clerical or related task, Section 4008.4 would indicate that the board may adopt a regulation authorizing a pharmacy technician to check the performance of this task.

Furthermore, the board could conclude that use of inpatient pharmacy technicians to check certain tasks performed by other inpatient pharmacy technicians is merely a method of quality control and does not constitute "supervision." Depending on the factual setting, the use of a peer to double check the quality of the work being performed may contain certain facets of supervision, however, it may also lack other important components related to control of the work being supervised.

Therefore, we conclude that a regulation may be adopted by the California State Board of Pharmacy pursuant to Section 4008.5 of the Business and Professions Code to allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians.

Very truly yours,

Bion M. Gregory
Legislative Counsel

By
Francisco A. Martin
Deputy Legislative Counsel

FAM:tfh

Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes

PETER J. AMBROSE, FRANK G. SAYA, LARRY T. LOVETT, SANDY TAN, DALE W. ADAMS, AND RITA SHANE

Abstract: The accuracy rates of board-registered pharmacy technicians and pharmacists in checking unit dose medication cassettes in the inpatient setting at two separate institutions were examined.

Cedars-Sinai Medical Center and Long Beach Memorial Medical Center, both in Los Angeles county, petitioned the California State Board of Pharmacy to approve a waiver of the California Code of Regulations to conduct an experimental program to compare the accuracy of unit dose medication cassettes checked by pharmacists with that of cassettes checked by trained, certified pharmacy technicians. The study consisted of three parts: assessing pharmacist baseline checking accuracy (Phase I), developing a technician-training program and certifying technicians who completed the didactic and practical training (Phase II), and evaluating the accuracy of certified technicians checking unit dose medication cassettes as a daily function (Phase III).

Twenty-nine pharmacists and 41 technicians (3 of whom were pharmacy interns) participated in the study. Of the technicians, all 41 successfully completed the didactic and practical training, 39 successfully completed the audits and became certified checkers, and 2 (including 1 of the interns) did not complete the certification audits because they were reassigned to another work area or had resigned. In Phase II, the observed accuracy rate and its lower confidence limit exceeded the predetermined minimum requirement of 99.8% for a certified checker. The mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The difference in mean accuracy rates between pharmacists (99.52%; 95% confidence interval [CI] 99.44–99.58%) and technicians (99.89%; 95% CI 99.87–99.90%) was significant ($p < 0.0001$).

Inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

Index terms: Administration; Dispensing; Drug distribution systems; Personnel, pharmacy; Pharmacists, hospital; Pharmacy, institutional, hospital; Professional competence

Am J Health-Syst Pharm. 2002; 59:1183-8

The rapidly changing health care environment necessitates that health care organizations optimize limited resources while improving the quality of care provided. Medication-related complications cost the American health care system as much as $177 billion annually.[1] Pharmacist expertise in drug therapy has repeatedly demonstrated improved patient outcomes, fewer complications, and better control of the cost of medication use.[2-4] However, there currently is a critical shortage of pharmacists, as documented in the Department of Health and Human Services report to Congress on the pharmacist workforce.[5] This shortage is especially acute in California, where the ratio of 58 pharmacists to 100,000 people in the population is well below the national average of 71 pharmacists to 100,000 people in the population. In this same report, the Pharmacy Manpower Project Aggregate Demand Index for California indicated a high

PETER J. AMBROSE, PHARM.D., FASHP, is Clinical Professor, Department of Clinical Pharmacy, School of Pharmacy, University of California San Francisco (UCSF), San Francisco. FRANK G. SAYA, PHARM.D., FASHP, is Manager, Pharmacy Services, Cedars-Sinai Medical Center (CSMC), Los Angeles, CA. LARRY T. LOVETT, PHARM.D., is Manager, ScriptCare Pharmacy, Huntington Beach, CA. SANDY TAN, PHARM.D., is Manager, Pharmacy Services, CSMC. DALE W. ADAMS, PHARM.D., is Vice President, Medical Operations, and Director, Pharmacy Services, Long Beach Memorial Medical Center and Miller Children's Hospital, Long Beach, CA, and Assistant Dean, Department of Clinical Pharmacy, School of Pharmacy, UCSF. RITA SHANE, PHARM.D., FASHP, is Director, Pharmacy Services, CSMC, and Assistant Dean, Department of Clinical Pharmacy, School of Pharmacy, UCSF.

Address correspondence to Dr. Ambrose at the Department of Pharmacy Services, Long Beach Memorial Medical Center, 2801 Atlantic Avenue, P.O. Box 1428, Long Beach, CA 90801-1428.

The contributions of Caroline Chellamy, Pharm.D., Judy Muraszko, Pharm.D., Dennis W. Mackewicz, Pharm.D., Donna Luong, Pharm.D., and the inpatient pharmacy staff at Cedars-Sinai Medical Center and Long Beach Memorial Medical Center are acknowledged.

Presented to the California State Board of Pharmacy, Los Angeles, CA, January 24, 2001.

level of demand for pharmacists. The current shortage of pharmacists poses a significant challenge to providing and maintaining the desired level of pharmaceutical care.[6]

The importance of pharmacy technicians in ensuring the efficient operation of hospital pharmacies is widely recognized. By reassigning nondiscretionary drug distribution tasks to pharmacy technicians, pharmacists can be redeployed to prevent adverse drug events and ensure optimal medication use. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. Pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacist shortage. Expanding the role of technicians by implementing a structured training program with ongoing quality assurance measures may ease the impact of the pharmacist shortage through the judicious and appropriate use of skilled support personnel and increase the time available to pharmacists to perform clinical functions.

Background

In 1997, the California State Board of Pharmacy was petitioned to authorize board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In response to strong opposition from some professional organizations and community pharmacists, who were concerned that the exemption could be expanded outside of the inpatient pharmacy environment and jeopardize pharmacist jobs, the board voted not to grant this petition. However, the board did express a desire to receive additional evidence to further evaluate allowing pharmacy technicians to perform this function. Thus, Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMMC) petitioned the board to grant a waiver of the California Code of Regulations to conduct an "experimental program" under the direction of the University of California, San Francisco, School of Pharmacy. The purpose of the program was to compare the accuracy of unit dose medication cassettes checked by pharmacists with those checked by trained, registered pharmacy technicians in the inpatient setting. In May 1998, the waiver was granted for the experimental program known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The waiver was initially granted through November 1, 2000, and was extended to December 2002 on the basis of data generated from this study, which was presented to the board in January 2001.

CSMC is a 900-bed, acute tertiary care hospital in Los Angeles, California, and LBMMC is a 540-bed, acute tertiary care hospital in Long Beach, California. The unit dose drug distribution system used by CSMC and LBMMC is diagrammed in Figure 1. It should be emphasized that the process of filling and checking unit dose medication cassettes is preceded by the review and verification of all medication orders by a pharmacist. The pharmacist evaluates the appropriateness of the medication, dose, dosage form, route of administration, and frequency in the order and screens for drug allergies, drug–drug interactions, and contraindications. A pharmacist is also responsible for dispensing any initial medication doses needed before the regularly scheduled unit dose cart distribution.

Pharmacy technicians do not evaluate the accuracy and appropriateness of medication orders. Pharmacy technicians perform manipulative and nondiscretionary functions only under the supervision of pharmacists. When filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. Next, a "checker" verifies the filled cassette against the fill list to minimize the possibility of errors before the medications are sent to the nursing areas. In California, only a pharmacist can check these unit dose cassettes, which necessitated the waiver from the board of pharmacy to allow technicians to perform this function in this program. It should be noted that nurses also check the medication when removing it from a patient's cassette and confirm it with the medication administration record (also reviewed and approved by a pharmacist) before administering the medication to the patient, in accordance with Joint Commission on Accreditation of Healthcare Organizations and California Department of Health Services requirements. Thus, a medication is triple-checked before it is administered to a patient.

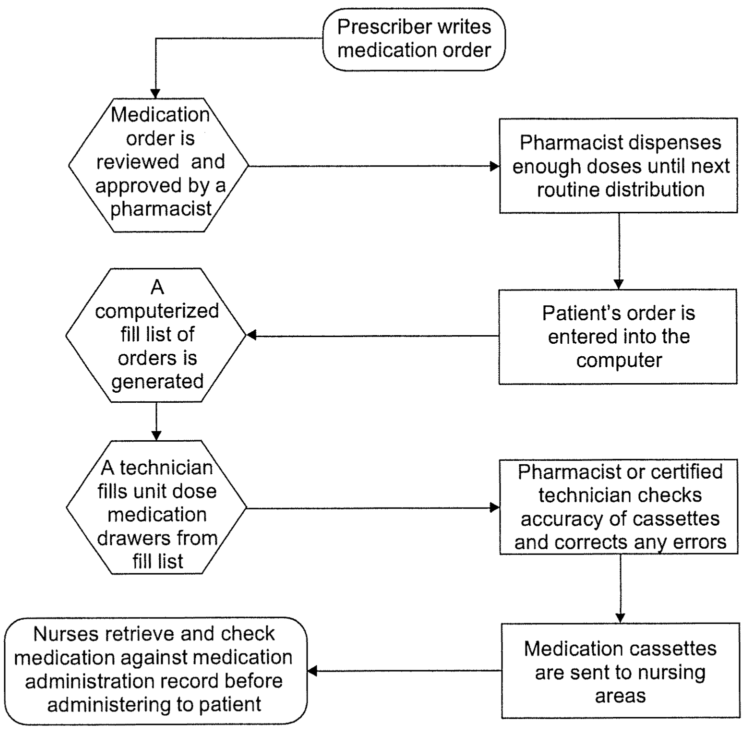
This article describes the experimental program and the accuracy of trained technicians checking unit dose medication cassettes compared with that of pharmacists.

Methods

This study was conducted concurrently at both CSMC and LBMMC and consisted of the following three phases, which were modeled from previous studies[7-13]:

- Phase I: Assessing the baseline accuracy rate of pharmacists checking unit dose medication cassettes,
- Phase II: Developing a technician training program for checking unit dose cassettes and certifying technicians who successfully completed the training program, and

Figure 1. Diagram of the inpatient unit dose drug distribution system used at both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center in normal practice and during the study.



- Phase III: Evaluating the accuracy of certified technicians checking unit dose medication cassettes by conducting quality assurance audits.

Phase I began in June 1998 with the goal of auditing a minimum of 12,500 doses at each institution. Staff pharmacists checked all unit dose cassettes filled by technicians as was the pharmacists' normal routine during the day shift. They were aware that audits were being conducted. Study participants were selected on the basis of their normal work schedules, and no attempt was made to alter assignments. In addition to any spontaneous errors made by technicians filling the cassettes, artificial errors were randomly introduced by pharmacist "auditors" assigned to oversee the study process. Artificial errors were introduced at a rate of at least one error per 500 doses (0.2%) to coincide with a 99.8% minimum accuracy rate.[7] The pharmacist checkers documented and corrected any errors they detected. Subsequently, the pharmacist auditor would audit and verify the accuracy of the pharmacist checker in detecting and correcting artificial and spontaneous filling errors for all doses dispensed during the audit period. Spontaneous and artificial errors overlooked by the pharmacist checkers were documented on an audit form and corrected by the pharmacist auditors before the medication cassettes were distributed to the nursing stations. There were a total of three pharmacists at CSMC and five at LBMMC who were responsible for introducing artificial errors and auditing the pharmacists. In all three phases of the study, an error was defined as a wrong drug, dose, quantity, or dosage form; expired medication; inaccurate concentration; wrong patient's medication cassette; or missing drug.

During Phase II of the program, the pharmacy services departments at CSMC and LBMMC collaborated on a training syllabus, qualifying examination, and data collection forms. Technicians and pharmacy interns (employed and functioning as technicians) were eligible to be included in the study if they were registered with the California State Board of Pharmacy and had at least six months of experience filling unit dose medication cassettes. They were then given didactic and practical training, in accordance with the approach used by the Minnesota Society of Hospital Pharmacists in a pilot project in which technicians were trained to check unit dose cassettes filled by other technicians.[7] The didactic component consisted of lectures on the unit dose process, proper packaging and repackaging techniques, medication safety, and basic pharmaceutical calculations. The didactic training concluded with an examination. Technicians were required to achieve a minimum passing score of 80% on the examination. The practical training included observing a pharmacist checking unit dose cassettes and actual hands-on experience. After successful completion of the didactic and practical training, the technicians were audited for accuracy in checking unit dose cassettes for at least 3500 consecutive doses. Artificial errors, as described for Phase I of the program, were also introduced in this process. The audits were conducted by the same pharmacist auditors as in Phase I. To become a certified technician checker in this program, an overall accuracy rate of at least 99.8% was required. This phase of the study began in June 1998 and was continued as new technicians were trained and included in the program.

Phase III began in April 1999. In this phase, certified technician checkers were responsible for checking unit dose medication cassettes as a daily activity while under the supervision of a pharmacist. Monthly quality assurance audits of at least 500 doses were conducted for each certified technician checker, using the same procedure of introducing random artificial errors as previously described. Accuracy was to be maintained at 99.8% or higher. If a certified technician checker failed a monthly audit, the audit was to be repeated within 30 days. If the technician failed the second audit, the technician would be removed from the checking position until he or she was retrained and recertified. If a certified technician checker did not perform this function for more than three months, an audit would be conducted when the technician restarted checking medication cassettes. If a technician had not checked cassettes for more than six months, recertification was required.

In January 2000, the board approved the following requested amendment to the program: "In Phase III of the study, a monthly audit will be conducted for 3 months, and if the accuracy rate meets or exceeds the minimum target of 99.8% for three consecutive audits, future audits will be conducted quarterly thereafter for that technician. Technicians failing a quarterly audit will have to pass three consecutive monthly audits before resuming quarterly audits." The amendment had been requested by CSMC and LBMMC, since no certified technician had failed a monthly audit.

Error rates were calculated as the number of errors discovered by the auditors divided by the total number of unit doses audited. The accuracy rate was defined as one minus the error rate, which was then converted to a percentage. The 95% confidence intervals for these rates and p values for comparing the pharmacist and technician checkers were computed using SAS, version 6.12 (SAS Institute, Cary, NC). An additional analysis was conducted to ensure that wide variation in accuracy rates among individual technicians did not exist, since this could result in a favorable mean accuracy rate and mask the performance of one or more technicians who performed below the established goal of 99.8%. Mixed-effects logistic regression models with a random-checker effect were used to confirm the results.

Results

Twenty-nine pharmacists (15 at CSMC, 14 at LBMMC) participated in Phase I of the study to supply baseline data of the checking accuracy of pharmacists. A total of 41 technicians (24 at CSMC, 16 at LBMMC, and 1 working at both), three of whom were interns, participated in Phase II of the study. All 41 technicians successfully completed the didactic training, 39 successfully completed the audits and became certified checkers for Phase III, and 2 technicians (including 1 of the interns) did not complete the certification audits because they were reassigned or had resigned.

Table 1 lists the combined-institution accuracy rates of pharmacist and technician checkers in Phase I and II, respectively. For technicians, both the observed average accuracy rate and its lower confidence limit exceeded the minimum requirement of 99.8% for a certified checker. The difference in accuracy rates between pharmacists and technicians was significant ($p < 0.0001$). Interestingly, the mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The two pharmacy interns had accuracy rates of 99.89% and 99.97%. One technician had an accuracy rate of 99.75%, which was just below the target rate, and subsequently met the minimum requirement and became certified after the next audit.

In Phase III, all certified technicians at both institutions maintained a minimum accuracy of 99.8% during their monthly and quarterly audits. Phase III began in April 1999; through December 2001, no certified technician checker had failed any quality assurance audits. However, some technicians were removed from the list of certified checkers during the study period because of work reassignments or other non-study-related issues. The board of pharmacy was continually updated on the names of certified technician checkers in the semiannual reports submitted.

Discussion

The proposition of allowing trained technicians to check unit dose medication cassettes filled by other technicians has been hotly debated in California in the past decade (appendix). This study's results appear to support the ability of well-trained technicians to accurately check unit dose medications.

Several studies have been published evaluating the accuracy of pharmacy technicians in checking other technicians in a unit dose medication fill system.[7-13] Our results corroborate the findings from these studies; in fact, we observed a higher accuracy rate for technicians than for pharmacists ($p < 0.0001$). The boards of pharmacy in Kansas, Minnesota, and Washington currently allow technicians to check unit dose medication cassettes filled by other technicians. In addition, the American Society of Health-System Pharmacists and the

Table 1.
Accuracy of Pharmacists and Technicians in Checking Unit Dose Medication Cassettes

Checker	No. Participants	No. Doses Checked	Mean Accuracy Rate(%)[a]	95% Confidence Interval (%)
Pharmacists	29	35,829	99.52	99.44–99.58
Technicians[b]	39	161,740	99.89	99.87–99.90

[a]The difference in accuracy rates between pharmacists and technicians is significant ($p < 0.0001$), using mixed-effects logistic regression models.
[b]Includes two pharmacy interns who were employed and functioning as technicians.

California Society of Health-System Pharmacists (professional policy 9801, October 1998) support the role of the technician in checking unit dose medication cassettes.

The expansion of the technician's role has been shown to increase pharmacists' productivity.[14] We estimated that pharmacists at each institution spent approximately one hour per day per pharmacist checking unit dose medication cassettes before the program was implemented. In this experimental program, the pharmacists were able to use this additional time to expand clinical services and respond to drug therapy-related requests from physicians, such as dosing recommendations. The training and auditing of technicians for checking medication cassettes are centralized and carried out by the technician supervisor, who is under the direction of a pharmacist manager. By centralizing this responsibility, decentralized pharmacists gain additional time for direct patient care activities. Also, pharmacists at both institutions have reported an increase in job satisfaction after implementing the experimental program.

When evaluating the study results, some limitations should be acknowledged. The pharmacist checkers selected to determine the baseline accuracy rate of checking unit dose medication cassettes were those who happened to be staffing the inpatient areas on the dates that the audits were performed. Neither the pharmacist checkers nor the dates of the audits were randomized. The pharmacists and the technicians were cognizant of the study, although they did not necessarily know when audits were to be conducted. Artificial errors introduced were not randomized using a random numbers table but were based on the judgment of the pharmacist auditors who attempted to introduce a variety of different errors. The auditors at each institution introduced errors independently. In addition, the severity of errors was not defined in the study; therefore, this information was not included in the results.

The results of this study were presented to the California State Board of Pharmacy, which is now reconsidering allowing technicians to check unit dose cassettes filled by other technicians in the inpatient setting, under the same conditions of this study. The waiver for this study expires in December 2002. Until state regulations are changed or the expiration date is reached, both institutions will continue to gather data from the quarterly audits.

Conclusion

In this study, we concluded that pharmacy technicians who had been trained and certified in a closely supervised program that incorporates quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

References

1. Ernest FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost of illness model. *J Am Pharm Assoc.* 2001; 41:192-9.
2. Leape LL, Cullen DJ, Clapp MD et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999; 282: 267-70.
3. Agency for Healthcare Research and Quality. Making healthcare safer: a critical analysis of patient safety practices; the clinical pharmacist's role in preventing adverse drug events. www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf (accessed 2001 Aug 4).
4. Rudis MI, Brandl KM. Position paper on critical care pharmacy services. *Crit Care Med.* 2000; 28:3746-50.
5. U.S. Department of Health and Human Services. The pharmacist workforce: a study of the supply and demand for pharmacists. Report to Congress. http://bhpr.hrsa.gov/healthworkforce/pharmacist.html (accessed 2001 Aug 2).
6. Advisory Board daily briefing. Pharmacist shortage may increase risk of medication errors. www.dailybriefing@advisory.com (accessed 2001 Aug 27).
7. Woller TW, Stuart J, Vrabel R et al. Checking of unit dose cassettes by pharmacy technicians at three Minnesota hospitals. *Am J Hosp Pharm.* 1991; 48:1952-6.
8. Lovett LT, Spangler LC. System for checking the accuracy of filled unit dose cassettes by pharmacy technicians. Paper presented at ASHP Midyear Clinical Meeting. San Francisco, CA; 1980 Dec 11.
9. Grogan JE, Hanna JA, Haight RA. A study of accuracy of pharmacy technicians working in a unit dose system. *Hosp Pharm.* 1978; 13:194-9.
10. Ness JE, Sullivan SD, Stergachies A. Accuracy of technicians and pharmacists in identifying dispensing errors. *Am J Hosp Pharm.* 1994; 51:354-7.
11. Spooner SH, Emerson PK. Using hospital pharmacy technicians to check unit dose carts. *Hosp Pharm.* 1994; 29:433-4,436-7.
12. Becker MD, Johnson MH, Longe RL. Errors remaining in unit dose carts after checking by pharmacists versus pharmacy technicians. *Am J Hosp Pharm.* 1978; 35:432-4.
13. Gray SL, Parker PE. A Kansas hospital's certification of technician checking technician in unit dose cart-fill. *J Kans Pharm.* 1994; 68:8. Abstract.
14. Kalman MK, Witkowski DE, Ogawa GS. Increasing pharmacy productivity by expanding the role of pharmacy technicians. *Am J Hosp Pharm.* 1992; 49:84-9.

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians

Year	State Regulation
Before 1993	Acute care hospitals in California were permitted to allow technicians to check the accuracy of technician-filled inpatient unit dose medication cassettes, under chart order exemption in the pharmacy regulations.
1993	The use of inpatient pharmacy technicians to check technicians filling unit dose cassettes was deemed unacceptable by the California State Board of Pharmacy, as evidenced by the following correspondence provided to the California Association of Hospital and Health Systems: "Please note the law does not authorize a technician to check another technician. While a technician may check another technician, the final check must always be done by a pharmacist."

Continued on next page

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians *(continued)*

Year	State Regulation
1994	The Hospital Pharmacy Committee of the California State Board of Pharmacy proposed draft language to add a section to the California Code of Regulation (CCR1717) to allow pharmacy technicians to check the work of other pharmacy technicians in connection with filling unit dose medication cassettes for patients whose orders had been previously reviewed by a pharmacist.
1995	This draft language was presented in May at a board of pharmacy informational hearing.
1996	In June, as a result of failure to reach agreement over the proposed language, the board developed a technician committee. This committee was charged to evaluate the entire pharmacy technician program including changes necessary to improve the program, discuss and plan for future changes and roles of technicians, and pursue any statute or regulatory changes necessary to accommodate these practices. The committee, in an October report to the board, recommended several potential changes including asking the board to consider allowing technicians to check the work of other technicians for unit dose medication cassette filling under a waiver system that included specific provisions (e.g., functions). In response to this report, the board of pharmacy voted to move forward with regulatory action to allow technicians to check the accuracy of technicians' work in a unit dose medication cassette fill system. During this time, the board of pharmacy began to enforce the California Code of Regulations relating to the use of technicians for checking of unit dose medication cassettes and required facilities to discontinue the practice.
1997	In May, responding to requests from multiple health systems and the California Society of Health-System Pharmacists, the board of pharmacy gave notice of its intent to amend regulations to allow technician checking of technician-filled unit dose medication cassettes. All interested parties were provided an opportunity to provide oral testimony at the proposal hearing in July. At that time, the board of pharmacy did not approve moving forward with the amended regulations. In response to the many delays in reaching consensus to change current regulations, representatives from LBMMC and CSMC developed the proposal in collaboration with the University of California, San Francisco, School of Pharmacy to perform a study in order to provide the board with objective data.
1998	On May 27, the board granted the requested waiver of the California Code of Regulations to conduct the "experimental program." The waiver was initially granted until November 1, 2000. However, the waiver was subsequently extended until February 1, 2001.
2001	In January, having reviewed the results of this study, the board extended the waiver until December 2002.

Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting
Summary of Results
June 21st 2004 - May 22nd 2005

A Collaborative Study Between
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SCHOOL OF PHARMACY
and the
Pharmacy Services Department of
CEDARS-SINAI MEDICAL CENTER

Background

- Study to determine the impact of pharmacists on prevention of medication errors during the equivalent time spent on checking medication cassettes

- 2 year study (waiver) allows technicians to check technicians filled medication cassettes

- The number and types of medication errors prevented at the prescribing step (order written by the physician) and at the administration step (medication administered by the nurse) of the medication use process will be reported

Study Objectives

- Determine top 10 drugs involved in potential prescribing and administration errors
- Determine type and frequency of medication ***errors intercepted*** at the prescribing and administration steps
- Compare ***intercepted errors*** with USP MedMARX data on errors
- Evaluate factors contributing to prescribing and medication administration errors
- Evaluate potential harm that could have resulted if error was not intercepted

Medication Related Encounters

June 21st 2004 - May 22nd 2005 (48 weeks)

Total Medication Related Encounters: **28,969 (603/week)**

- Potential Errors Intercepted (prevented): **1296**

Medication Prescribing :	885 (68%)
Medication Administration:	411 (32%)

- Other Medication Related Encounters :

Pharmacist dosing per MD request:	25,342
STAT orders:	360
Rounds:	58
Code Blue:	29
Drug Information:	1661

Medication Prescribing
Potential Errors Intercepted
June 21st 2004 - May 22nd 2005 (48 weeks)

- Potential prescribing errors prevented by the pharmacist: 885
- Orders requiring clarification: 534 (type of error not specified)
- Types of medication ***errors intercepted which prevented****:

Wrong Dose	48.9 %	Medication Contraindicated	3.1 %
Allergy Contraindication	21.7 %	Drug Interaction	2.3 %
Necessary medications not ordered	11.7 %	Wrong Frequency/Rate	2.0 %
Duplication in therapy	5.7 %	Wrong Drug	0.6 %
Wrong Route	4.0 %		

* In those situations where error type was specified

Additionally, there were 57 incomplete orders requiring clarification.

Examples of Medication Prescribing Errors Prevented

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Ganciclovir: 5mg/kg iv q12h pt s/p kidney transplant & renal insufficiency	Pharmacist recommended 2.5mg/kg/day for CMV induction	*Avoided adverse drug reaction (ADR) from overdose*
Oxaliplatin (chemotherapy) dosage in patient with renal insufficiency	Pharmacist recommended dosage adjustment	*Avoided ADR due to excessive dose of chemotherapy*
Celebrex ordered in patient with sulfa allergy	Pharmacist recommended alternative	*Avoided morbidity associated with an allergic reaction*
Ceftazidime ordered as 1 gm q8h for meningitis in young patient	Pharmacist recommended 2 gm q8h to achieve adequate effect	*Avoided sub-optimal treatment, possible mortality/morbidity*
Lovenox 40 mg daily ordered in patient with chronic renal failure	Pharmacist recommended change to Heparin	*Avoided increased risk of bleeding in patient already receiving blood transfusions*

Medication Administration
Potential Errors Intercepted
June 21st 2004 - May 22nd 2005 (48 weeks)

Potential medication administration errors prevented by a pharmacist: 411 encounters

Types of medication ***errors intercepted which prevented:***

Omission of Dose	41.2 %
Transcription Error	13.9 %
Wrong Dose	8.1 %
Wrong Patient	6.0 %
Extra Dose	7.9 %
Delay in Dose	5.7 %
Wrong Rate	5.5 %
Wrong Drug	4.8 %
Drug to be given to patient was not ordered	3.8 %
Wrong Route	3.1 %

Examples of Medication Administration Errors Prevented

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Pt. scheduled for chemotherapy in AM.	Pharmacist identified that chemo was not given	*Avoided omission of chemotherapy*
Pt was about to receive Tobramycin at a 12 hr interval; order was for q24h	Pharmacist notified nurse that dose was to be given every 24 hr	*Avoided potential renal (kidney) toxicity*
PCA pump was programmed incorrectly	Pharmacist notified nurse	*Avoided potential adverse events associated with excessive narcotic dose*
Pt receiving Potassium Chloride 60meq infusion; order was for 20meq	Pharmacist notified nurse to change infusion	*Avoided potential hyperkalemia and cardiac arrest*
Nurse transcribed Kayexalate when Kaopectate ordered	Pharmacist notified nurse about transcription error	*Avoided potential hypokalemia and cardiac toxicity*

Results compared to USP MedMARX Data

Leading types of errors include:

	USP MedMarx Data 2003[1]	Research Study
Omission error	24 %	22.7 %
Improper dose/quantity	23 %	26.4 %
Unauthorized drug	10 %	2.1 %
Extra dose	5 %	4.2 %
Wrong patient	5 %	3.3 %
Wrong route	2 %	3.4 %

1. http://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=9223078&message_id=63691&user_id=USP

TOP 10 Medications/Classes

June 21st 2004 - May 22nd 2005 (48 weeks)

Top 10 medications/classes involved in potential prescribing and administration errors

Medication Prescribing

- Chemotherapy
- Electrolytes
- Enoxaparin (Lovenox)
- Vancomycin
- Warfarin
- Levofloxacin
- Neupogen
- Fluconazole
- Cefepime
- TPN

Medication Administration

- Vancomycin
- Heparin
- Chemotherapy
- Electrolytes
- TPN
- Erythropoietin
- Warfarin
- Fluconazole
- Insulin
- Levofloxacin

Preliminary Evaluation of Potential Patient Outcomes

Pharmacist prevented medications errors associated with potential harm: 422

No Harm	340
Temporary Harm	387
Permanent Harm	11
Increase in Length of Stay	23
Death	1
Type of harm unspecified	534

Factors Contributing to Prescribing Errors

- Incomplete patient information
- Drug allergies overlooked
- Wrong drug name, dosage form or abbreviation
- Incorrect dosage calculations
- Incorrect dosage frequency
- Laboratory results not checked prior to ordering medications
- Concomitant therapy (e.g. supportive drugs for chemotherapy) necessary to prevent adverse reactions not ordered

Factors Contributing to Administration Errors

- Two patient identifiers not used
- Illegible orders
- Drug name confusion
- Incorrect pump programming
- Patients transferred and orders not transcribed accurately
- Environmental factors- distractions, interruptions and significant workload
- Staffing issues- such as shift changes and floating staff

Summary of Study Results to Date

Results of the 48 week study demonstrates the impact of pharmacists on prescribing and administration errors:

- 1296 errors intercepted by the pharmacist
- 27450 medication related encounters including dosing of medications per MD request, participation in codes, rounds and drug information questions
- Preliminary evaluation of outcomes: 422 pharmacist encounters prevented potential harm of which:
  - 387 prevented temporary harm
  - 11 prevented permanent harm
  - 23 prevented an increase in length of stay
  - 1 prevented death

Blank

California Pharmacists Association

Uniting the Profession of Pharmacy

January 26, 2006

California State Board of Pharmacy
Legislation and Regulation Committee

Re: Tech check tech regulatory proposal

Dear Committee Members,

CPhA rigorously supports efforts to promote the value of pharmacists' intervention and care to improve patient health and safety in all practice settings. Consistent with this goal and policy adopted by CPhA's House of Delegates (attached), we support the regulatory change to allow tech check tech programs in the acute care inpatient setting in hospitals with ongoing clinical pharmacy programs.

To ensure that the clinical pharmacy programs result in pharmacists spending more time on patient care in the inpatient setting, we strongly urge the Board to include in the regulation language a requirement that facilities/hospitals with tech check tech provide the Board with a pharmacy services plan describing the clinical pharmacy programs. In addition, the regulation should require the Board to actively review and monitor these programs to ensure that the best interests of the public health and safety are being served. To be clear, we support this change in the law only in the acute care hospital inpatient setting. The regulation should specify that it does not apply to outpatient clinic pharmacy services, LTC pharmacy services, home IV therapy pharmacy services, or any other sub-acute service or outpatient pharmacy.

Pharmacists fear that without these additions, hospital administrations may decide to eliminate, rather than more fully utilize, some of their pharmacists to achieve potential cost savings. Should hospitals pursue this course, the result would be to decrease patient care and safety rather than enhance it as the rationale for this proposal suggests.

This change highlights a much greater and urgent need in California pharmacy practice. The entire body of law and regulation regarding Pharmacy Technicians needs to be fully reworked. CPhA and CSHP have agreed to begin work shortly on drafting new language on more standardized education, qualifications for technician licensure and other issues. In addition, we will be exploring legislative and regulatory proposals to allow greater flexibility for pharmacies in utilizing pharmacy technicians. We will welcome the involvement of other interested parties. We request the participation and support of the Board as we move forward with this reform.

Sincerely,

Lynn Rolston, CEO

4030 Lennane Drive
Sacramento, California 95834
916.779.1400 • Fax 916.779.1401
www.cpha.com • cpha@cpha.com

California Pharmacists Association

Uniting the Profession of Pharmacy

CPhA House of Delegates Policy **January 26, 2006**

04-14 <u>Pharmacy Technicians</u>

The California Pharmacists Association supports the following:

1. The pharmacist shall retain those functions involving judgmental decisions, and accept full responsibility for the direct supervision and activities of technical or clerical functions, which are performed by pharmacy technicians.
2. Minimal qualifications for pharmacy technicians shall include graduation from a nationally accredited pharmacy technician vocational training program that meets Board of Pharmacy standards and PTCB certification.
3. All pharmacy technicians, regardless of practice setting, must be registered with the California Board of Pharmacy.
4. When the health and welfare of the patient can be enhanced by utilizing pharmacy technicians, they should be utilized.
5. The standard ratio of pharmacist to technician shall not exceed 1:2. Should a "Pharmacist-in-Charge" desire to use more pharmacy technicians than this ratio, the pharmacy must have a pharmacy services plan approved by the California State Board of Pharmacy.
6. Individuals convicted of crimes which suggest a predisposition to committing illegal acts involving drugs or which, due to the nature or severity of the offense, subject the individual to pressure which could lead to drug-related crimes shall be denied access to prescription drugs as pharmacy technicians. However, evidence of rehabilitation shall be considered a mitigating factor.
7. Technicians checking the work of other technicians only in instances where technicians with recognized certification (e.g., PTCB) are checking other technicians in an inpatient hospital setting, with clinical pharmacy services, and the work being checked is limited to the filling of a unit dose drug distribution system. Legal responsibility and liability for any "Tech-Check-Tech" program shall include the holder of the pharmacy permit, and the "Pharmacist-in-Charge" and technicians involved. Any "Tech-Check-Tech" program shall include specific written guidelines and continuous quality improvement (CQI) programs. Further, all "Tech-Check-Tech" programs shall establish and maintain a verifiable system which assures the ongoing monitoring and documentation of technician performance.

4030 Lennane Drive
Sacramento, California 95834
916.779.1400 • Fax 916.779.1401
www.cpha.com • cpha@cpha.com

Testimony to Request to Amend 16 CCR § 1793.7 and 1793.8

Submitted to the Legislation and Regulation Committee
California State Board of Pharmacy

January 26, 2006

Presented by
Susan Ravnan, Pharm. D., FCSHP
Associate Professor, University of Pacific
Director of Government and Professional Affairs Externship, CSHP

BOP Testimony
January 26, 2006

Good afternoon, My name is Susan Ravnan. I am an associate professor at the University of the Pacific School of Pharmacy in Stockton and I am serving in an externship as Government and Professional Affairs Director for the California Society of Health System Pharmacists. I am here to provide supporting testimony to the Legislation and Regulation committee regarding the proposed regulations to enhance patient medication safety in the hospital setting by freeing health system pharmacists from checking unit dose and ward stock medications filled by health system technicians and deploying them to the patient care area to provide direct medication management.

I would first like thank the board and committee for devoting their valuable time and resources over the last 10 years to this important consumer protection issue and to commend you on the outstanding and thorough assembly of the board's history relating to this topic.

I have provided you with additional information today in varied formats to help facilitate your understanding of the patient medication safety regulations proposed.

In that packet of information you will see a cover page highlighting pertinent facts related to how this regulation improves patient medication safety. Additional information and references are also provided to assist you in your review and understanding of this issue as it rests in 2006 throughout the nation.

I would like to divert for a moment to a compelling 1966 quote from Linwood F. Tice, Dean of the Philadelphia College of Pharmacy and Sciences. " …The pharmacist of tomorrow will function by reason of what he knows, increasing the efficiency and safety of drug therapy and working as a specialist in his own right. It is in this direction that pharmaceutical education must evolve without delay."

Over the next 40 years academia has met the challenge and has unequivocally gone beyond this vision and educated pharmacists to be medication management experts.

The material I am providing today is just a sampling of the unquestionable benefit health system pharmacists and health system technicians play in health care and patient medication safety. The material demonstrates that:

- A 43% decline in hospital deaths transpired as a result of direct medication management by health system pharmacists
- 1 death per day is prevented by a health system pharmacist in the hospital.
- 66% of medication errors occur when the prescriber writes the order.
- 32% of medication errors occur when the medication is administered to the patient in the hospital
-

When health system pharmacists provide direct medication management, medication **errors** adversely affecting patient outcomes **decrease by 94%**
The prevailing issue is how can direct medication management by health system pharmacists be increased to improve medication safety. One way is by the help of properly trained health system pharmacy technicians. Health system pharmacy technicians play a vital role in medication safety because they allow the profession to better use health system pharmacists to manage medication therapy. One example of how they improve medication safety is through checking unit dose and floor stock medications in the hospital setting. For well over 10 years, 5 states, which currently utilize health system pharmacy technicians to check unit dose medications, report no adverse patient outcomes. Health system pharmacy technicians demonstrate a **99.88% accuracy** unit dose checking rate in the inpatient setting.

The bureau of labor statistics predicts that pharmacy technician employment will grow by 36% between 2000-2010 and one of the main reasons for this is an increased concern about safe medication use.

Health system pharmacy technicians began their initial training in the 1940's. Over the years, this training evolved and in the 1980's the American Society of Health System Pharmacists formally established health system technician training guides for health system pharmacists. Currently, there are over 247 academic pharmacy training programs as well as board certification and licensure for pharmacy technicians. Certified technicians are also required to complete 20 hours of continuing education every two years.

Therefore to ensure the highest quality of inpatient medication safety, health system pharmacists and health system technicians need to be utilized to the fullest extent of their education, training and expertise. That is achieved by providing a regulatory framework that ensures that health system pharmacists provide direct medication management to patients and health system technicians provide technician supervised nondiscretionary support.

CSHP is encouraged that the board recognizes this as a critical Consumer Protection issue and has demonstrated their support of inpatient health system pharmacy technicians checking unit dose medications legislation. We believe, however, that the proper venue and authority should be addressed in the regulatory arena and request that the committee move forward and recommend approval of this regulation to the full board.

CSHP | CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

Medication Management by Pharmacists in the Inpatient Setting Decreases Hospital Deaths

ISSUES:

- Pharmacists are medication experts that play a vital role in ensuring optimal patient care.
- The pharmacist's specialized medication knowledge is misplaced and underutilized if the pharmacist is not present in the patient care area.
- Pharmacy technicians should assist pharmacists with nondiscretionary tasks to facilitate safe medication use.

PROBLEM:

- Changes in health care, increased complexity of medication regimens and complex pharmacological properties, workforce shortage of pharmacists, physicians and nurses all contribute to increased medication prescribing errors.
- Pharmacy education has evolved to undertake these changes but pharmacists in the inpatient setting continue to be relegated to non-discretionary tasks at the expense of direct medication management.
- As a result, access to pharmacist's expertise in the inpatient setting is underutilized resulting in the increased incidence of medication errors.

FACT:

- In hospital mortality is decreased when pharmacists provide direct medication management.
- Medication errors that adversely affect patient outcomes decreased by 94% when pharmacists are involved in direct medication management.
- Pharmacists decrease medication prescribing errors by 66%.
- Pharmacy technicians demonstrated an accuracy checking rate of 99.88%.
- The safety of pharmacy technicians checking unit dose medications has been long-established in five states.

SOLUTION:

- Ensure high quality patient care by providing the infrastructure to allow pharmacist to be released to provide more direct medication management, by allowing properly trained and supervised technicians to check the filling of unit dose distribution systems and floor stock in inpatient settings.

725 30th STREET, SUITE 208, SACRAMENTO, CA 95816-3842
TEL.916.447.1033, FAX.916.447.2396, cshp@cshp.org, www.cshp.org

Detailed Documentation of the Pharmacists impact on Medication Safety

- A 43% decline in mortality was noted when the clinical staffing level increased from 0.34 FTE/100 occupied beds to 3.23 FTE/100 occupied beds.[1,2]

- Hospitals having pharmacists in patient care areas is associated with a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affected patient outcomes.[3]

- Rate of preventable prescribing medication errors is decreased by 66% when the pharmacist is full member of the patient care team in medical ICUs.[4,10]

- Physicians state that pharmacists in patient care areas could prevent 94% of potential adverse drug events.[5]

- 99% of recommendations made by pharmacists are accepted by physicians.[4]

- Pharmacists have greater impact when they provide their expertise earlier in the patient care decision process.[4]

- Most medication errors happen when prescribers write orders and nurses administer medications.[4,6,10]

- The Pharmacy Manpower Project continues to stress a workforce shortage of pharmacists and as the clinical role of pharmacists evolves the need for more pharmacists will continue to rise.[7]

- Society of Critical Care Society Medicine endorsed the need for pharmacists in the ICU to provide direct medication management.

Detailed Documentation of the Technicians impact on Medication Safety

- Trained and Certified Pharmacy technicians demonstrate a 99.88% unit dose checking accuracy. [8]
- California requires a high school diploma and one of the following: an associate's degree in pharmacy technology, training course specified by the board of pharmacy or a pharmacy technician certification prior to licensing a pharmacy technician.
- Hospital pharmacy technicians have existed since the 1950's establishing the importance of nondiscretionary support provided by technicians in the hospital setting.
- Formal training programs for hospital pharmacy technicians was established in the 1940's.[9]
- In the 1980's American Society of Health System Pharmacists established a technician training guide for hospital pharmacists.
- Currently there are approximately 247 technician academic training programs and Board Certification for pharmacy technicians.

Detailed Documentation of Technicians Checking Unit Dose Medications from Other States

- Washington- 1994 the Board of Pharmacy adopted regulations allowing technicians to check unit dose medication after appropriate training. Technicians must demonstrate 99% accuracy in medication checking.

- Minnesota- Regulations state that pharmacy technicians may perform functions that do not involve professional pharmaceutical judgment. The program has been in affect over 14 years with no complaints. The program resulted in increasing the number of pharmacists contributing to patient care.

- Kentucky- Legislation approving technician checking technician. No complaints have been in over 10 years.

- South Carolina- Board Policy and Procedure #140- Certified Pharmacy Technicians may check a technician's refill of a medication if the medication is to be administered by a licensed health care professional in an institutional setting.

- Kansas- Regulation to allow pharmacist-in-charge to develop policies and procedures for technicians

Support for California to Adopt Patient Medication Safety Regulations

- Five states utilize pharmacy technicians to check unit dose medication, including regulations adopted by Washington which has a legislative system that most closely parallels California.

- Pharmacy technicians have preformed nondiscretionary checking functions for over 14 years in other states without incidence.

- A California study demonstrated 99.88% accuracy rate of pharmacy technicians checking unit dose medication cassettes.

- Literature clearly demonstrates that pharmacist involvement in direct medication management decreases medication errors and reduces mortality.

- Interim results from California demonstrate that approximately 1,300 medication errors were prevented when pharmacists provided direct medication management.

- In the inpatient setting, an RN or LVN also verifies that the medication they are administering to their patient is correct, hence a triple check in hospital settings.

- 68% of medication errors occur when the prescriber writes the order. 38% of medication errors occur when the medication is administered to the patient.

- Pharmacists providing direct medication management will greatly decrease medication errors.

Attachments:

1. Bond C.A. et al. Clinical Pharmacy Services and Hospital Mortality Rates: Pharmacotherapy 1999;19: 556-64.
2. Bond C.A. et al. Interrelationships among Mortality Rates, Drug Costs, Total Cost of Care, and Length of Stay in United States Hospitals: Summary and Recommendations for Clinical Pharmacy Services and Staffing Pharmacotherapy 2001;21: 129-41.
3. Bond C.A. et al. Medication Errors in United States Hospitals Pharmacotherapy 2001;21: 1023-36.
4. Leape LL.et al. Pharmacists Participation on Physician Rounds and Adverse Events in the Intensive Care Unit. JAMA 1999;282:267-70.
5. Krupicka MI, et al. Impact of a pediatric clinical pharmacist in the pediatric intensive care unit. Crit Care Med 2002;30:919-21.
6. Lesar TS, et al. Medication Prescribing errors in a Teaching Hospital: A 9-Year Experience. Arch Intern Med 1997;157:1569-76.
7. Kenreigh CA, et al. The Pharmacist Shortage: Where do we Stand? www.medscape.com/viewarticle/521115. Accessed 1/25/06
8. Ambrose PJ, et al. Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes. Am J Health-Syst Pharm 2002;59:1183-8.
9. White Papers on Pharmacy Technicians 2002: Needed change can no longer wait. Am J Health-Syst Pharm 2003;60:37-51.
10. Kuckarslan SN, et al. Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units. Arch Intern Med 2003;263:2014-2018.

SPECIAL ARTICLE

Clinical Pharmacy Services and Hospital Mortality Rates

C. A. Bond, Pharm.D., FASHP, FCCP, Cynthia L. Raehl, Pharm.D., FASHP, and Todd Franke, Ph.D.

We evaluated the associations between clinical pharmacy services and mortality rates in 1029 United States hospitals. A data base was constructed from Medicare mortality rates from the Health Care Financing Administration and the National Clinical Pharmacy Services data base. A multivariate regression analysis, controlling for severity of illness, was employed to determine the associations. Four clinical pharmacy services were associated with lower mortality rates: clinical research ($p<0.0001$), drug information ($p=0.043$), drug admission histories ($p=0.005$), and participation on a cardiopulmonary resuscitation (CPR) team ($p=0.039$). The actual number of deaths (lower) associated with the presence of these four services were clinical research 21,125 deaths in 108 hospitals, drug information 10,463 deaths in 237 hospitals, drug admission histories 3843 deaths in 30 hospitals, and CPR team participation 5047 deaths in 282 hospitals. This is the first study to indicate that both centrally based and patient-specific clinical pharmacy services are associated with reduced hospital mortality rates. This suggests that these services save a significant number of lives in our nation's hospitals.
(Pharmacotherapy 1999;19(5):556–564)

The vision statement of the American College of Clinical Pharmacy (ACCP) states, "We will be the recognized leader in initiating, fostering, and disseminating pharmacotherapy innovations that will optimize patient care outcomes."[1] In addition, the 1998–2000 ACCP strategic plan considers "research that assesses the value of clinical pharmacy services" to rank fifth of 57 objectives.[1] Although substantial numbers of clinical studies found improved patient care and, in some cases, reduced costs at individual clinical sites,[2-27] few attempted to evaluate clinical pharmacy services in several sites or in an entire health care system. Such studies are critical to determine how these services affect health care.

In addition, a significant limitation of site-specific demonstration studies is that the results may be influenced by the patients, health care professionals, health care delivery system, or other site-specific factors. Thus, the benefits of the services may not be readily transferable to other clinical sites or settings. Hospital-based mortality rates are an important health care outcome measure, applicable to most hospital settings.

A literature review back to 1966 found four studies that evaluated the impact of clinical pharmacy services on mortality rates for hospitalized patients.[18, 28-30] Two of them[18, 28] examined the effect of a clinical pharmacist on mortality rates in an individual hospital, and neither concluded that a statistically significant effect existed. According to the other two studies, mortality rates were reduced with increased pharmacist staffing and provision of drug information services in 718 hospitals[29] and with increased pharmacist staffing in 3763 hospitals.[30] In the latter, the reduced mortality

From the Departments of Pharmacy Practice (Drs. Bond and Raehl) and Psychiatry (Dr. Bond), Schools of Pharmacy and Medicine, Texas Tech University Health Sciences Center–Amarillo, Amarillo, Texas; and the Department of Biostatistics and Biometrics, School of Public Policy and Social Research, University of California at Los Angeles, Los Angeles, California (Dr. Franke).

Address reprint requests to C. A. Bond, Pharm.D., Department of Pharmacy Practice, Texas Tech University Health Sciences Center-Amarillo, 1300 South Coulter Street, Amarillo, TX 79106.

was independent (specific contribution of pharmacists) of staffing levels of other health care professionals.[30]

Other studies were limited to exploring the associations among demographics, teaching affiliation, ownership, staff education and training, disease, quality of care, staffing, and fiscal characteristics.[31-38] Although hospital mortality is not a specific measure of quality of care, it does have a close association with quality.[35-39] Outcome measures must adjust for the influence of patient characteristics.[35, 37, 40, 41] If outcome measures (e.g., hospital mortality rates) do not adjust for severity of illness, conclusions for hospitals that treat severely ill patients would be inaccurate, leading to erroneous conclusions about the quality of care provided in those institutions.

We tested the association between mortality rates adjusted for severity of illness for Medicare patients in 1029 hospitals in the United States and 14 clinical pharmacy services.[42] This is one of the first studies to explore this relationship.

Methods

Sources of Data

The Medicare Hospital Mortality Information data tape for 1992 was purchased from Health Care Financing Administration (HCFA) and provided individual hospital Medicare mortality rates.[43] Methods used by HCFA to calculate mortality rates are published elsewhere.[44] Data for 14 clinical pharmacy services were obtained from the 1992 National Clinical Pharmacy Services (NCPS) data base, which is the largest hospital-based pharmacy data base in the United States.[42] The NCPS survey was updated from previous surveys[45, 46] and pretested by 25 directors of pharmacy. It was then mailed to the director of pharmacy in each acute care, general-medical surgical hospital listed in the American Hospital Association's (AHA) Abridged Guide to Health Care.[47] Study methodology, variables, and demographic results of this study are available elsewhere.[42] These two data bases were integrated into one, and SAS, release 6.11, implemented on a personal computer (Pentium 166 Mz), was used for statistical analysis.[48]

The HCFA provided 1992 Medicare mortality data for 5505 hospitals in 1992 (general medical-surgical, pediatric, psychiatric, alcohol and drug rehabilitation, etc.).[43] The AHA listed 4822 general medical-surgical hospitals in 1992.[47] Data from AHA and HCFA mortality data bases were able to be matched for 3763 hospitals, which constituted 100% of hospitals that could potentially be included in the study population. Hospitals included in this study had information on Medicare mortality rates and 14 clinical pharmacy services obtained from the NCPS data base.[42] Only general medical-surgical hospitals were used, to provide more homogeneous hospital and patient populations. Mortality rates for psychiatric, alcohol and drug rehabilitation, or rehabilitation hospitals would not be appropriate outcome measures of care. From the 1597 hospitals in the NCPS data base[42] and the 3763 hospitals matched from the HCFA and AHA data bases,[43, 47] data were matched for 1029 hospitals based on the presence of both Medicare mortality data and 14 clinical pharmacy services. These 1029 hospitals constituted the study population.

Variables and Analysis

Centrally delivered clinical pharmacy services used in the analysis were drug use evaluation (DUE), in-service education, drug information, poison information, and clinical research. Patient-specific clinical pharmacy services were adverse drug reaction monitoring, pharmacokinetic consultations, drug therapy monitoring, drug protocol management, total parenteral nutrition team participation, drug counseling, cardiopulmonary resuscitation (CPR) team participation, medical rounds participation, and admission drug histories. We defined clinical services specifically to indicate active participation by pharmacists in patient care. The Appendix gives definitions of clinical pharmacy services.

Simple and multiple regressions were used. Severity of illness was controlled by forcing three variables into the regression analysis model: percentage of intensive care unit (ICU) days (calculated as ICU days divided by total inpatient days), annual number of emergency room visits divided by the average daily census, and percentage of Medicaid patients (calculated as Medicaid discharges divided by total discharges). These variables were previously validated as measures of severity of illness in similar studies.[29, 30, 37-42] We chose them because they are the only ones validated as adjusters for severity of illness using these national data bases.[29, 30, 37, 38] Although other variables have been used to adjust for severity of illness with smaller patient populations (e.g., Acute Physiology and Chronic Health Evaluation [APACHE] scores, specific

Table 1. Severity of Illness, Clinical Services, Clinical Service Eligibility, and Increase or Decrease in Clinical Services in 1029 Hospitals

		% of Patients Who May Receive the Service[a]	% Increase in Service[b]
Severity of illness	Mean ± SD		
ICU days/total inpatient days	0.05 ± 0.04		
Number of emergency room visits/ADC	193.38 ± 114.63		
Medicaid discharges/total discharges	0.13 ± 0.09		
Predicted mortality/1000 admissions	87.51 ± 11.44		
Clinical pharmacy services	No. (%)		
Central clinical pharmacy services			
Drug use evaluation	978 (95.0)	5.3 ± 9.6	5.6
In-service education	687 (66.8)	8.6 ± 28.1	4.6
Drug information	237 (23.0)	4.1 ± 17.9	50.0
Poison information	161 (15.7)	0.2 ± 11.5	7.1
Clinical research	108 (10.5)	2.7 ± 8.9	44.5
Patient-specific clinical pharmacy services			
Adverse drug reaction monitoring	690 (67.1)	66.9 ± 44.0	47.8
Pharmacokinetic consultations	544 (52.9)	48.9 ± 44.5	35.0
Drug therapy monitoring	441 (42.9)	56.0 ± 39.4	7.3
Drug protocol management	355 (34.5)	48.0 ± 44.1	48.0
TPN team participation	325 (31.6)	55.1 ± 45.5	42.9
Drug counseling	310 (30.1)	33.8 ± 40.3	30.8
CPR team participation	282 (27.4)	67.6 ± 40.6	20.0
Medical rounds participation	153 (14.9)	27.3 ± 27.5	38.5
Admission drug histories	30 (2.9)	38.8 ± 43.0	50.0

ADC = average daily census.
[a]If the clinical service was present, the percentage of patients who were eligible to receive it.
[b]Percentage increase in hospitals offering service compared with the 1989 National Clinical Services data base.[46]

patient case mix, patient age, number of surgical patients, physician experience, length of shifts, patient workloads), they were not available through national data bases. Diagnosis-related groups are not reliable severity of illness adjusters since many hospitals have inflated these measures.

Statistical Analysis

A weighted least-squares regression was used to estimate and test relationships between clinical pharmacy services and observed mortality rates. The weight used in the analysis was the inverse of the variance for the observed mortality rate, $N/\{p \times (1 - p)\}$, where N was the number of Medicare admissions to the hospital and p was HCFA's expected mortality rate for each hospital. Parameter estimate 95% confidence intervals (CIs) were calculated for both simple and multiple regression analyses.

Regression results were calculated in two steps. First, parameter estimates for severity of illness variables were calculated by entering each variable into the model separately. Second, the remaining parameter estimates were calculated by entering them into the model separately after severity of illness variables were entered. Thus, all subsequent parameter estimates were adjusted for severity of illness indicators. This created a more accurate analysis of individual measures of association with mortality rates.

For multiple regression analysis, stepwise procedures were used to select variables for the model.[49, 50] Severity of illness variables were forced into the multiple regression model before other variables were allowed to enter. After their forced entry, stepwise regression was used to select the remaining variables. Variables selected through this method were confirmed by both forward- and backward-regression techniques, both of which selected the same set of variables. This analysis was used with severity of illness variables, because HCFA's mortality rates do not include accurate measures of severity of illness.[51, 52]

The correlation matrix for the independent variables and the variance inflation factor were used to examine the possible effects of multicollinearities among the variables. These indicated that there were no apparent problems among the set of independent variables. A detailed report of the analysis methods employed

Table 2. Simple Regression Analysis Controlling for Severity of Illness

Clinical Pharmacy Service	Slope	SE	Significance	95% CI
Severity of illness variables				
ICU days/total inpatient days	-0.003513	0.01	0.0001	-0.065, -0.005
Number of emergency room visits/ADC	0.000002	0.001	0.0001	0.000, 0.000
Medicaid discharges/total discharges	0.00157	0.001	0.011	0.004, 0.028
Central clinical pharmacy services				
Drug use evaluation	-0.000000	0.001	0.22	0.000, 0.000
In-service education	-0.000405	0.001	0.001	-0.006, -0.002
Drug information	-0.000881	0.001	0.0001	-0.011, -0.007
Poison information	-0.000157	0.001	0.0001	-0.004, 0.001
Clinical research	-0.001369	0.001	0.001	-0.016, -0.011
Patient-specific clinical pharmacy services				
Adverse drug reaction monitoring	-0.000358	0.001	0.001	-0.006, -0.001
Pharmacokinetic consultations	-0.000409	0.001	0.001	-0.006, -0.002
Drug therapy monitoring	-0.000407	0.001	0.0001	-0.006, -0.002
Drug protocol management	-0.000143	0.001	0.17	-0.004, -0.001
TPN team participation	-0.000572	0.001	0.0001	-0.008, -0.004
Drug counseling	-0.000631	0.001	0.001	-0.008, -0.004
CPR team participation	-0.000541	0.001	0.001	-0.008, -0.003
Medical rounds participation	-0.000945	0.001	0.0001	-0.012, -0.007
Admission drug histories	-0.00155	0.002	0.0001	-0.020, -0.011

ADC = average daily census.

with this study is published elsewhere (4864 hospitals and 3763 hospitals).[29, 30] Multiple regression analysis allowed us to determine which clinical pharmacy services explain mortality rates in United States hospitals. The intent was to build a multiple regression model to determine if these services were associated with hospital mortality rates.

A comparison of clinical pharmacy services that were statistically significant in the multiple regression model was developed further. Mean number of deaths/hospital/year, based on whether the hospital provided the clinical pharmacy service, is presented. Only services that had statistically significant associations with mortality rates (multiple regression model) were included in the analysis. The number of deaths/year was calculated from the difference in death rates (per admission) x mean number of admissions per hospital offering this service x number of hospitals offering the service. The a priori level of significance for all tests was set at 0.05.

Results

A total of 1029 hospitals (64%) of the 1597 general medical-surgical hospitals from the NCPS data base were matched from the 3763 hospitals from HCFA and AHA data bases (potential pool of study hospitals). These 1029 hospitals (27%) constituted the study population. The mean number of admissions/year/hospital was 8174 ± 6803, or 8,411,387 total admissions (35% of total U.S. admissions).[53] The mean annual mortality for hospitals was 89.09 ± 18.97 deaths/1000 admissions, or 728 deaths/hospital/year.

Table 1 shows severity of illness, clinical pharmacy services, extent that services were available to patients, and clinical pharmacy service growth. The presence of these services varied between 3% of hospitals providing drug admission histories and 95% providing DUE. Availability of clinical services also varied, with 12.7% of patients involved with pharmacist-conducted clinical research and 95% of patients provided with DUE services. All clinical pharmacy services increased (% of hospitals offering service) between 1989 and 1992.[42, 46] Services with the lowest and greatest increases were DUE (5.6% increase) and drug admission histories (50%), respectively.

Table 2 shows simple regression analysis for severity of illness, clinical pharmacy services, and mortality rates described as slope, standard error (SE), probability, and CI. The slope measures the rate of change for the variable and is expressed as either positive (presence of this service was associated with higher mortality rates) or negative (presence of this service was associated with lower mortality rates). All 14 clinical pharmacy services were associated with lower mortality rates, but these differences were not statistically significant for DUE and drug protocol management.

Table 3. Multiple Regression Analysis[a] for Clinical Pharmacy Services

Clinical Pharmacy Service	Slope	SE	Significance	95% CI
Severity of illness variables				
ICU days/total inpatient days	-0.36	0.014	0.009	-0.64, -0.01
Number of emergency room visits/ADC	0.00005	0.001	0.0001	0.000, 0.022
Medicaid discharges/total discharges	0.010	0.006	0.069	-0.004, 0.019
Central clinical pharmacy services				
Drug use evaluation	0.00001	0.000	0.11	0.000, 0.000
In-service education	0.001	0.001	0.616	-0.002, 0.003
Drug information	-0.002	0.001	0.043	-0.005, 0.000
Poison information	0.002	0.001	0.08	0.000, 0.000
Clinical research	-0.008	0.001	0.0001	-0.010, -0.005
Patient-specific clinical pharmacy services				
Adverse drug reaction monitoring	0.001	0.001	0.519	-0.003, 0.001
Pharmacokinetic consultations	0.001	0.001	0.544	-0.002, 0.003
Drug therapy monitoring	0.0005	0.001	0.64	-0.002, 0.003
Drug protocol management	-0.0003	0.001	0.759	-0.003, 0.002
TPN team participation	-0.001	0.001	0.48	-0.003, 0.001
Drug counseling	-0.001	0.001	0.254	-0.003, 0.001
CPR team participation	-0.002	0.001	0.039	-0.004, 0.000
Medical rounds participation	-0.003	0.001	0.054	-0.005, 0.000
Admission drug histories	-0.006	0.002	0.005	-0.010, -0.001

ADC = average daily census.
[a]R^2 = 22.4%, adjusted R^2 = 21.8%.

Table 3 shows multiple regression analysis for severity of illness variables, clinical pharmacy services, and mortality rates. For each parameter estimate, slope (rate of change), SE, probability, and CI are presented. Two clinical pharmacy services approached statistical significance, poison information (p=0.08) and medical rounds participation (p=0.054). Statistically significant associations were found with drug information services, clinical research, CPR team participation, and admission drug histories. These 4 provided the best regression equation (fit) for the 14 services studied. This regression model accounted for 22.4% of the total explainable variance associated with hospital mortality rates in the 1029 hospitals.

Table 4 shows the mean number of deaths/hospital/1000 admissions for hospitals having the four clinical pharmacy services that had a statistically significant association with reduced mortality (multiple regression analysis). The difference between the number of deaths (lower, calculated from Table 4) for hospitals having these four services was 195.61 deaths/year/hospital that had clinical research services, 44.15 deaths/year/hospital that had drug information services, 128.10 deaths/year/hospital that had drug admission histories, and 17.90 deaths/year/hospital that had CPR team participation. Hospitals that had these services had up to 40,478 fewer deaths (summed from number of deaths for each service) than those that did not.

Discussion

This study determined associations between clinical pharmacy services and mortality rates adjusted for severity of illness. All 14 services were associated with lower mortality rates in the simple regression model, but these differences were not statistically significant for DUE and drug protocol management. Four services were associated with lower hospital mortality rates in the multiple regression analysis: drug information services, clinical research, CPR team participation, and admission drug histories. Since mortality rates are associated with quality of care, these services are likely quality of care indicators for both hospitals and pharmacies.[35–39]

Reasons why clinical research was associated with reduced mortality rates are unknown. One possible explanation is that clinical research was primarily done in academic health care centers, as teaching hospitals are associated with lower mortality rates.[29, 36–40, 54] However, only 51 (47.2%) hospitals that had pharmacist-conducted clinical research were members of the Council of Teaching Hospitals. This suggests that other factors may be more important in explaining the association. Another possible explanation is that

Table 4. Deaths per Hospital with and without Clinical Pharmacy Services/1000 Admissions and Actual Number of Deaths/Year

Clinical Pharmacy Service	No. of Hospitals	No. of Admissions/Hospital/ Year with this Service (mean ± SD)	No. of Deaths/Hospital with this Service (mean ± SD)	No. of Deaths/Hospital without this Service (mean ± SD)	Total No. of Deaths/Year[a]
Clinical research	108	16,819 ± 8741	78.68 ± 20.45	90.31 ± 18.42	21,125
Drug information	237	11,349 ± 9311	86.09 ± 21.16	89.98 ± 18.18	10,463
Admission drug histories	30	14,878 ± 8365	80.73 ± 22.71	89.34 ± 18.80	3843
CPR team participation	282	8522 ± 7742	87.56 ± 21.99	89.66 ± 17.68	5047

[a]Calculated from the difference in death rate/admission (presence or absences of the clinical service) x mean number of admissions/hospital/year offering this service x number of hospitals offering the clinical service.

departments of pharmacy that conduct research may employ more highly educated and trained pharmacists (Pharm.D., residency, fellowship, etc.). Although no data on education and training levels and staffing were sought, directors of pharmacy who have earned a Pharm.D. degree provide higher levels of clinical pharmacy services in their hospitals compared with directors with other degrees.[42, 45, 46, 55]

The 195.61 deaths/year/hospital difference between hospitals that had pharmacist-conducted clinical research and those that did not resulted in 21,125 fewer deaths/year in the 108 hospitals that had pharmacist-conducted clinical research. If extrapolated to all of the 3763 hospitals in the potential pool of study hospitals, this would result in 736,080 fewer deaths possibly being associated with the presence of this service. The median yearly pharmacist salary cost/hospital for conducting clinical pharmacy research was $5656 and the mean yearly grant funding was $79,765 ± $128,641/hospital, a cost:benefit of 1:14 (every $1 of salary time resulted in $14 of grants).[56] Given the economic benefits to the hospital and the association with reduced mortality rates, more study seems warranted to determine why clinical research produces these benefits.

We do not know why pharmacist-provided drug information services were associated with lower mortality rates. An unbiased source of drug information may promote better patient care and thus reduce the number of deaths. Improved hospital information systems may reduce mortality rates.[57] The presence of this service may also indicate a medical staff more open to input from pharmacists. Finally, drug information services may indicate better formulary control of drug therapy with improved patient care.

The 44.15 deaths/year/hospital difference between hospitals that had pharmacist-provided drug information services and those that did not resulted in 10,463 fewer deaths/year in the 237 hospitals in which pharmacists provided the services. If extrapolated to all of the 3763 hospitals in the potential pool of study hospitals, this would result in 166,137 fewer deaths possibly being associated with the presence of the services. The median yearly pharmacist salary cost/hospital for providing drug information services was $8679, or $82/occupied bed/year.[56] This translates to $1.06/admission, or $196.58/additional death ($8,679/44.15).

The reason pharmacist-provided drug histories were associated with lower mortality rates is unknown. The service itself could account for this association, as up to 28% of all hospital admissions were attributed to drug-related morbidity and mortality.[58] In addition, studies suggest that adverse drug events in hospitals are often preventable if detected early,[59] and could be reduced by better information systems.[57] Perhaps pharmacists are better able to detect drug-related problems than other health care professionals.

The 128.10 deaths/year/hospital difference between hospitals that had pharmacist-provided drug histories and those that did not resulted in 3843 fewer deaths/year in the 30 hospitals that had the service. If extrapolated to all of the 3763 hospitals in the potential pool of study hospitals, this would result in 482,040 fewer deaths possibly being associated with this service. The median yearly pharmacist salary cost/hospital for providing drug histories was $8967, or $5/patient having an admission drug history.[56] This translates to $1.10/admission, or $70.00/additional death ($8967/128.10). Given the low cost of this service and the number of hospitalizations associated with drugs,[57-59] it is not clear why so few directors of pharmacy have implemented the service.

Nor do we know why pharmacist participation on the CPR team was associated with lower mortality rates. Perhaps having a pharmacist on codes promotes better drug therapy and saves more lives. The presence of this service may also indicate a medical staff more open to pharmacist input on drug therapy in critical care settings.

The 17.90 deaths/year/hospital difference between hospitals that had pharmacist participation on the CPR team and those that did not resulted in 5047 fewer deaths/year in the 282 hospitals that had such participation. If extrapolated to all of the 3763 hospitals in the potential pool of study hospitals, this would result in 67,358 fewer deaths possibly being associated with the presence of this service. The median yearly pharmacist salary cost/hospital for pharmacist participation on a CPR team was $639, or $8/patient receiving CPR.[56] This translates to $0.08/admission, or $35.70/additional death ($639/17.90).

Up to 40,478 deaths/year (lower) were seen in hospitals that had these clinical pharmacy services. Some caution should be advised in interpreting this number since this study was designed to show association, not cause and effect. In addition, we were able to obtain information only about clinical pharmacy services, and information about the services of physicians, nurses, and other health care professionals could not be obtained or evaluated. Nevertheless, the impact of these services should not be underestimated. If 22.4% of deaths were directly attributable to the services (R^2 for multiple regression model was 22.4%), the result is 9067 deaths (22.4% x 40,478).

This is the first study to demonstrate that both centrally based and patient-specific clinical pharmacy services are associated with reduced hospital mortality rates. It is also the first to quantify the potential impact (number of deaths) of the services.

Better models for adjusting mortality rates for severity of illness using more precise clinical and socioeconomic variables may be developed in the future. The total variance explained by our regression model (22.4%) was consistent with other studies: 11%,[34] 14–25%,[60] 17.26%,[30] and 21%.[40] Since this is one of the first studies comparing clinical pharmacy services with mortality rates in a large number of hospitals, the findings must be replicated in future studies. Caution should be employed in applying our findings to individual hospitals.

In summary, four clinical pharmacy services were associated with lower hospital mortality rates in our multiple regression model: drug information services, clinical research, CPR team participation, and drug admission histories. These services likely reflect better quality of care. Hospitals that had the services had up to 40,478 fewer deaths/year than those without them. The results suggest that clinical pharmacy services do save a significant number of lives in the country's hospitals. Given their significant benefits and low costs, it is our hope that clinical pharmacists and directors of pharmacy will develop and expand their clinical pharmacy services.

References

1. American College of Clinical Pharmacy. Vision statement. ACCP Rep 1997;16(10):S1–8.
2. Black BL. Resource book on progressive pharmaceutical services. Bethesda, MD: American Society of Hospital Pharmacists, 1986.
3. Hatoum HT, Catizone C, Hutchinson RA, et al. An eleven-year review of the pharmacy literature: documentation of the value and acceptance of clinical pharmacy. Drug Intell Clin Pharm 1986;20:33–48.
4. Comptroller General of the United States. Study of health facilities construction costs. Washington, DC: U.S. Government Printing Office, 1972:68–72, 363–79.
5. Barker KN, Pearson RE. Medication distribution systems. In: Brown TR, Smith MC, eds. Handbook of institutional pharmacy practice. Baltimore: Williams & Wilkins, 1986:325–51.
6. Elenbaas RM, Payne VW, Bauman JL. Influence of clinical pharmacists consultations on the use of blood level test. Am J Hosp Pharm 1980;37:61–4.
7. Bollish SJ, Kelly WN, Miller DE, et al. Establishing an aminoglycoside pharmacokinetic monitoring service in a community hospital. Am J Hosp Pharm 1981;38:73–6.
8. Abramowitz PA, Nold EC, Hatfield SM. Use of clinical pharmacists to reduce cefamandole, cefoxitin, and ticarcillin costs. Am J Hosp Pharm 1982;39:1176–80.
9. Mutchie KD, Smith KA, MacKay MW, et al. Pharmacists' monitoring of parenteral nutrition: clinical and cost effectiveness. Am J Hosp Pharm 1979;36:785–7.
10. Covinsky JO, Hamburger SC, Kelly KL, et al. Impact of docent clinical pharmacists on treatment of streptococcal pneumonia. Drug Intell Clin Pharm 1982;16:587–91.
11. Bond CA, Salinger RJ. Fluphenazine out-patient clinics: a pharmacist's role. J Clin Psychiatry 1979;40:501–3.
12. Herfindal ET, Bernstein LR, Kishi DT. Effect of clinical pharmacy services on prescribing on an orthopedic unit. Am J Hosp Pharm 1983;40:1945–51.
13. Avorn J, Soumerai SB. Improving drug-therapy decisions through educational outreach: a randomized controlled trial of academically based "detailing." N Engl J Med 1983;308:1457–63.
14. Knapp DE, Knapp DA, Speedie MK, et al. Relationship of inappropriate drug prescribing to increased length of hospital stay. Am J Hosp Pharm 1979;36:1334–7.
15. Knapp DE, Speedie MK, Yaeger DM, et al. Drug prescribing and its relationship to length of hospital stay. Inquiry 1980;17:254–9.
16. McKenney JM, Wasserman AH. Effect of advanced pharmaceutical services on the incidence of adverse drug reactions. Am J Hosp Pharm 1979;36:1691–7.
17. Clapham CE, Hepler CE, Reinders TP, et al. Economic consequences of two drug-use control systems in a teaching hospital. Am J Hosp Pharm 1988;45:2329–40.
18. Bjornson DC, Hiner WO, Potyk RP, et al. Effect of pharmacist on health care outcomes in hospitalized patients. Am J Hosp Pharm 1993;50:1875–84.
19. Jenkins MH, Bond CA. The impact of clinical pharmacists on

Appendix. Definitions of Terms

Central Clinical Pharmacy Services

Drug use evaluation: Check if, at minimum, drug use patterns are analyzed and results are reported to hospital committee.

In-service education: Pharmacist presents continuing education to fellow employees (M.D., R.N., R.Ph., etc) on a scheduled basis at least 4 times a year.

Drug information: Provided only if a formal drug information service with specifically assigned pharmacist(s) is available for questions. Does not require a physical location called drug information center.

Poison information: Provided only if a pharmacist is available to answer questions regarding toxicity or overdose on a routine basis with appropriate resources.

Clinical research: Is performed by pharmacists either as a principal investigator or coinvestigator. Pharmacist is likely to be (co-)author of a published paper. Do not check if activity is limited to investigational drug distribution or record keeping.

Patient-Specific Clinical Pharmacy Services

Adverse drug reaction management: Pharmacist evaluates potential adverse drug reaction while the patient is hospitalized and appropriately follows through with physicians.

Pharmacokinetic consultation: Provided if, only at a minimum, the drug regimen, serum level, and patient's medical record are reviewed, and verbal or written follow-up is provided when necessary.

Drug therapy monitoring: Provided only if a patient's medical record is reviewed and verbal or written follow-up is provided when necessary. Monitoring is continuing and repeated, often on daily basis. Do not check if only drug orders are reviewed. Does not include pharmacokinetic consults, total parenteral nutrition team, rounds, adverse drug reaction management, or drug therapy protocol management.

Drug protocol management: Pharmacist, under the order of a prescriber, requests laboratory tests as necessary and initiates or adjusts drug dosage to obtain the desired therapeutic outcome (e.g., aminoglycoside or heparin dosing/pharmacy).

Total parenteral team participation: Pharmacist, at a minimum, reviews patients' medical records with or without written or verbal follow-up as necessary.

Drug counseling: Pharmacist provides counseling either during hospitalizations or at time of discharge. Do not check if counseling involves only review of label directions.

CPR team participation: Pharmacist is an active member of the team, attending most arrests when present in the hospital.

Medical rounds participation: Pharmacist attends rounds with medical team at least 3 days/week, actively providing specific input.

Admission drug histories: Pharmacist provides admission histories.

psychiatric patients. Pharmacotherapy 1996;16(4):708–14.

20. Monson RA, Bond CA, Schuna A. Role of the clinical pharmacist in improving outpatient drug therapy. Arch Intern Med 1981;141:1441–4.
21. Bond CA, Monson R. Sustained improvement in drug documentation, compliance, and disease control—a four year ambulatory care model. Arch Intern Med 1984;144:1159–62.
22. Tang I, Vrahnos D, Hatoum H, et al. Effectiveness of clinical pharmacist interventions in a hemodialysis unit. Clin Ther 1993:15:459–64.
23. Brown WJ. Pharmacist participation on a multidisciplinary rehabilitation team. Am J Hosp Pharm 1994:51:91–2.
24. Garber AM, Fuchs VR, Silverman JF. Case mix, costs, and outcomes: between faculty and community services in a university hospital. N Engl J Med 1984:310:1231–7.
25. Pauly MV, Wilson P. Hospital output forecasts and the cost of empty hospital beds. Health Serv Res 1986;21:413–28.
26. Rich EC, Gifford G, Luxenberg M, et al. The relationship of hospital staff experiences to the cost and quality of inpatient care. JAMA 1990;263:953–7.
27. Watts CA, Klastorin TD. The impact of case-mix on hospital costs: a comparative analysis. Inquiry 1990;17:357–67.
28. Boyko WL, Yurkowski PJ, Ivey M, et al. Pharmacist influence on economic and morbidity outcomes in a tertiary care teaching hospital. Am J Health-Syst Pharm 1997:54:1591–5.
29. Pitterle ME, Bond CA, Raehl CL, Franke T. Hospital and pharmacy characteristics associated with mortality rates in United States hospitals. Pharmacotherapy. 1994;14(5):620–30.
30. Bond CA, Raehl CL, Pitterle ME, Franke T. Health care professional staffing, hospital characteristics, and hospital mortality rates. Pharmacotherapy 1999;19(2):130–8.
31. Carter JH, Mills AC, Homan SM, et al. Correlating the quality of care with nursing resources and patient parameters: a longitudinal study. NLN Publ 20-2191,1987:331–45.
32. Kelly JV, Hellinger FJ. Physician and hospital factors associated with mortality of surgical patients. Med Care 1986;24:785–800.
33. Rhee SO. Factors determining the quality of physician performance in patient care. Med Care 1976;14:733–50.
34. Shortell SM, Hughes EFX. The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. N Engl J Med 1988;318:1100–7.
35. Dubois RW, Brooks RH, Rodgers WH. Adjusted hospital death rates; a potential screen quality of medical care. Am J Public Health 1987;77:1162–7.
36. Krakauer H, Bailey RC, Skellan KJ, Stewart JD, Hartz AJ. Evaluation of the HCFA model for the analysis of mortality following hospitalization. Health Serv Res 1992:27(3):317–35.
37. Hartz AJ, Gottlieb M, Kuhn ER, Rimm A. National validation study of Medicare mortality studies (project 1247-M). Technical report to the Health Standards and Quality Review Bureau. Washington, DC, 1989.
38. Hartz AJ, Krakauer H, Kuhn EM, et al. Hospital characteristics and mortality rates. N Engl J Med 1989;321:1720–5.
39. Keeler EB, Rubenstein LV, Kahn KL, et al. Hospital characteristics and quality of care. JAMA 1992;268:1709–14.
40. Green J, Wintfield N, Sharkey P, Passman LJ. The importance of severity of illness measures in assessing hospital mortality. JAMA 1990;262:241–6.
41. Green J, Passman LJ, Wintfield N. Analyzing hospital mortality—the consequences of diversity in patient mix. JAMA 1991;265:1849–53.
42. Bond CA, Raehl CL, Pitterle ME. 1992 National Clinical Pharmacy Services study. Pharmacotherapy 1994;14(3):282–304.
43. Health Care Financing Administration. Medicare hospital mortality information on data tape. Washington, DC: U.S. Government Printing Office, 1992.
44. Health Care Financing Administration. Medicare hospital mortality information, 1991. Washington, DC: U.S. Government Printing Office, 1992.

45. Raehl CL, Bond CA, Pitterle ME. Hospital pharmacy services in the Great Lakes region. Am J Hosp Pharm 1990;47:1283–1303.
46. Raehl CL, Bond CA, Pitterle ME. Pharmaceutical services in U.S. hospitals in 1989. Am J Hosp Pharm 1992;49:323–46.
47. American Hospital Association. American Hospital Association abridged guide to the health care field data tape. Chicago: Author, 1992.
48. SAS Institute Inc. SAS, version 6.11. Cary, NC: Author, 1996.
49. Wampole BE, Freund RD. Use of multiple regression in counseling psychology research: a flexible data analytic strategy. J Counsel Psychol 1987;34:372–82.
50. Pedhazur EJ. Multiple regression in behavioral research: explanation and prediction, 2nd ed. New York: Harcourt Brace Jovanonich, 1982.
51. Greenfield S, Aronow HU, Elashoff RM, Watanaabe D. Flaws in mortality data: hazards of ignoring comorbid disease. JAMA 1988;260:2253–5.
52. Kenlel P. Hospitals balk at mortality report results. Modern Healthcare January 1, 1988:5–6.
53. American Hospital Association. Hospital statistics, 1992. Chicago: Author, 1993.
54. Rosenthal GE, Harper DL, Quinn LM, Cooper GS. Severity-adjusted mortality and length of stay in teaching hospitals and nonteaching hospitals: results of a regional study. JAMA 1997;278:485–90.
55. Pitterle ME, Bond CA, Raehl CL. Pharmaceutical care index measuring comprehensive pharmaceutical care. Am J Hosp Pharm 1992;46:2226–9.
56. Bond CA, Raehl CL, Pitterle ME. Cost of pharmaceutical services in U.S. hospitals in 1992. Am J Hosp Pharm 1995;52:603–13.
57. Leape LL, Bates DW, Cullen DJ, et al. System analysis of adverse drug events. JAMA 1995;274:35–43.
58. Johnson JA, Bootman JL. Drug related morbidity and mortality. Arch Intern Med 1995;155:1949–56.
59. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events JAMA 1995;274:29–34.
60. Daley J, Jencks S, Draper D, et al. Predicting hospital-associated mortality for Medicare patients. JAMA 1988;260:3617–24.

SPECIAL ARTICLE

Interrelationships among Mortality Rates, Drug Costs, Total Cost of Care, and Length of Stay in United States Hospitals: Summary and Recommendations for Clinical Pharmacy Services and Staffing

C. A. Bond, Pharm.D., FASHP, FCCP, Cynthia L. Raehl, Pharm.D., FASHP, FCCP, and Todd Franke, Ph.D.

We evaluated interrelationships and associations among mortality rates, drug costs, total cost of care, and length of stay in United States hospitals. Relationships between these variables and the presence of clinical pharmacy services and pharmacy staffing also were explored. A database was constructed from the 1992 American Hospital Association's Abridged Guide to the Health Care Field, the 1992 National Clinical Pharmacy Services database, and 1992 Health Care Finance Administration mortality data. A severity of illness-adjusted multiple regression analysis was employed to determine relationships and associations. Study populations ranged from 934–1029 hospitals (all hospitals for which variables could be matched). The only pharmacy variable associated with positive outcomes with all four health care outcome measures was the number of clinical pharmacists/occupied bed. That figure tended to have the greatest association (slope) with reductions in mortality rate, drug costs, and length of stay. As clinical pharmacist staffing levels increased from the tenth percentile (0.34/100 occupied beds) to the ninetieth percentile (3.23/100 occupied beds), hospital deaths declined from 113/1000 to 64/1000 admissions (43% decline). This resulted in a reduction of 395 deaths/hospital/year when clinical pharmacist staffing went from the tenth to the ninetieth percentile. This translated into a reduction of 1.09 deaths/day/hospital having clinical pharmacy staffing between these staffing levels, or $320 of pharmacist salary cost/death averted. Three hospital pharmacy variables were associated with reduced length of stay in 1024 hospitals: drug protocol management (slope -1.30, p=0.008), pharmacist participation on medical rounds (slope -1.71, p<0.001), and number of clinical pharmacists/occupied bed (slope -26.59, p<0.001). As drug costs/occupied bed/year increased, severity of illness-adjusted mortality rates decreased (slope -38609852, R^2 8.2%, p<0.0001). As the total cost of care/occupied bed/year increased, those same mortality rates decreased (slope -5846720642, R^2 14.9%, p<0.0001). Seventeen clinical pharmacy services were associated with improvements in the four variables.

(Pharmacotherapy 2001;21(2):129–141)

Numerous studies reported relationships between various components of total cost of care and mortality rates,[1-5] but none evaluated the total cost of care in a large population of United

States hospitals. A MEDLINE search could not identify any studies in which the association between drug costs and mortality rates were explored in a large number of hospitals. In addition, no studies evaluated mortality rates, drug costs, total cost of care, and length of stay together in a large number of hospitals. We explored the interrelationships among these variables and summarized relationships between them and the presence of clinical pharmacy services and pharmacy staffing. The association between clinical pharmacy services and pharmacy staffing on length of hospital stay were explored in detail.

Data from 1992 and 1989 showed that pharmacist staffing and certain clinical pharmacy services had a direct relationship and were associated with reduced hospital mortality rates.[6-8] In addition, increased staffing levels of clinical pharmacists and certain clinical pharmacy services had a direct relationship and were associated with reduced drug costs in U.S. hospitals.[9] Finally, increased staff levels of pharmacy administrators and clinical pharmacists and the presence of six clinical pharmacy services had a direct relationship and were associated with reduced total cost of care.[10]

Length of hospital stay provides some measure of the hospital's efficiency. In addition, it is important when analyzing the hospital's profit structure. If two hospitals have the same average daily census, but one of them has a 20% shorter length of stay, that hospital would have 20% more admissions and about the same cost structure. In a capitated reimbursement model, the hospital with 20% more admissions would be able to bill for 20% more patients than the one with longer stay. Our other studies on mortality rates,[6-8] drug costs,[9] and total cost of care[10] did not measure efficiency.

Whereas a substantial number of studies documented the benefits of pharmacists and clinical pharmacy services at individual clinical sites,[11-39] only a few determined the beneficial effects of pharmacists and clinical pharmacy services on major heath care outcome variables in a large number of hospitals.[6-10] Studies of large numbers of hospitals are critical, since they are not subject to bias of patient populations, quality of health care professionals, physical facilities, structure, and process that may confound studies conducted in individual sites. In addition, when analyzed together, multihospital studies provide a road map as to which clinical pharmacy services are likely to be successful in most hospitals. This study analyzed new relationships and associations between these health outcome variables and clinical pharmacy services and pharmacy staffing. Associations between pharmacy staffing and clinical pharmacy services on length of stay are provided since these data have not been published previously.

Methods

Sources of Data

Data for 14 clinical pharmacy services and pharmacist staffing were obtained from the 1992 National Clinical Pharmacy Services database.[40] Methods of analyzing data are available elsewhere.[40-42] Mortality rate information was obtained from the Health Care Finance Administration (HCFA).[43] Admissions data, occupancy rates, length of stay, and total cost of care for each hospital were obtained from the American Hospital Association's (AHA) abridged guide to healthcare.[44] The National Clinical Pharmacy Services (NCPS) survey instrument was updated from previous surveys and pretested by 25 directors of pharmacy.[41, 42] The questionnaire was mailed to the director of pharmacy in each acute care, general medical-surgical hospital listed in the AHA database.[44] Study methodology, variables, and demographic results of this study are available elsewhere.[40-42] The NCPS database is the largest hospital and clinical pharmacy database in the U.S. These databases were integrated into one database, and SAS, release 6.12, implemented on a personal computer, was used for all statistical analyses.[45] All data were for inpatients only.

The AHA listed 4822 general medical-surgical hospitals in 1992.[44] Variables from the AHA database were matched for 3444 hospitals (demographic, severity of illness) that constituted hospitals that could be included in these study populations (100%). Hospitals included in these studies had information on 14 clinical pharmacy services and pharmacist staffing from the NCPS database[40]; length of stay, demographic, and severity of illness variables

From the Department of Pharmacy Practice, School of Pharmacy, Texas Tech University Health Sciences Center–Amarillo. Amarillo, Texas (Drs. Bond and Raehl); and the Department of Biostatistics and Biometrics, School of Public Policy and Social Research, University of California at Los Angeles, Los Angeles, California (Dr. Franke).

Address reprint requests to C. A. Bond, Pharm.D., Department of Pharmacy Practice, School of Pharmacy, Texas Tech University Health Sciences Center–Amarillo, 1300 S. Coulter Street, Amarillo, TX 79106.

from the AHA database[44]; and HCFA Medicare mortality data.[43] Only general medical-surgical hospitals were used so as to provide more homogeneous information. Mortality rates, costs, and length of stay information for psychiatric, alcohol and drug rehabilitation, or rehabilitation hospitals would not be appropriate since they are substantially different from general medical-surgical hospitals.[44] From 1597 hospitals in the 1992 NCPS database, 3444 in the AHA database, and 4822 from HCFA, 1029 hospitals were matched for mortality data,[8] 934 for drug cost data,[9] 1016 for total cost of care data,[10] and 1024 for length of stay data. These hospitals constituted the study populations.

Variables and Analysis

Centrally delivered clinical pharmacy services used in the analysis were drug use evaluation, in-service education, drug information, poison information, and clinical research. Patient-specific clinical pharmacy services were adverse drug reaction (ADR) monitoring, pharmacokinetic consultations, drug therapy monitoring, drug protocol management, total parenteral nutrition (TPN) team participation, drug counseling, cardiopulmonary resuscitation (CPR) team participation, medical rounds participation, and admission drug histories. We defined clinical pharmacy services specifically to indicate active participation by the pharmacist in patient care. Definitions for these clinical pharmacy services are shown in Appendix 1.

Hospital pharmacist staffing data were taken from full-time equivalent (FTE) data collected in the NCPS database survey.[40] Hospital pharmacy administrators were defined as FTE pharmacy directors, assistant directors, and supervisory pharmacists; dispensing pharmacists as FTE pharmacists who spent most of their work time (> 50%) primarily in dispensing activities; and clinical pharmacists as FTE pharmacists who spent most of their work time (> 50%) providing clinical pharmacy services (nondispensing). Each category was mutually exclusive. Staffing data were for inpatients only.

Severity of illness was controlled by forcing three variables into the multiple regression analysis model: percentage of intensive care unit (ICU) days (calculated as ICU days divided by total inpatient days), annual number of emergency room visits divided by the average daily census, and percentage of Medicaid patients (calculated as Medicaid discharges divided by total discharges). These variables were validated as severity of illness measures in similar studies.[1, 3, 4, 6-10, 46, 47] They were chosen because they are the only ones validated as adjusters for severity of illness using these national databases.[1, 3, 4, 6-10, 46, 47] Other variables have been used to adjust for severity of illness with smaller patient populations (Acute Physiology and Chronic Health Evaluation [APACHE] scores, specific patient case mix, patient age, number of surgical patients, physician experience, length of shifts, patient work loads, etc.), but they were not available for the study hospitals. Diagnosis-related groups are not reliable severity of illness adjusters since many hospitals have inflated these measures.

Patient care outcome measures must adjust for patient characteristics that influence the outcome measure.[48-50] If outcome measures (e.g., length of stay) do not adjust for severity of illness, conclusions for hospitals that treat severely ill patients would be inaccurate, leading to erroneous conclusions about the health care provided by professionals in these institutions.

Statistical Analyses

Severity of illness-adjusted multiple regression analysis was used. All multiple regression models (previous work,[6-10] length of stay, interrelationships among mortality rates, drug costs, total cost of care, length of stay, hospital pharmacy staffing) used the severity of illness-adjusted model. For multiple regression analysis, stepwise procedures were used to select variables for the model.[51, 52]

Severity of illness variables were forced into the multiple regression model before any other variables were allowed to enter. A weighted least squares regression was used to estimate and test relationships among hospital and pharmacy staffing, clinical pharmacy services, and mortality rates.[7, 8] The weight used in the analysis was the inverse of the variance for the observed mortality rate, $N/\{p \bullet (1 - p)\}$, where N was the number of Medicare admissions to the hospital and p was HCFA's expected mortality rate for each hospital. Methods used for these mortality models are discussed in depth elsewhere.[6-8]

After forced entry of severity of illness variables, stepwise regression was used to select remaining variables. Variables selected through this method were confirmed by forward- and backward-regression techniques, both of which selected the same set of variables. The

Table 1. Summary of Significant Associations Among Clinical Pharmacy Services, Pharmacy Staffing, and Mortality Rates, Drug Costs, Total Cost of Care, and Length of Stay

	Mortality Rate[8] (1029 hospitals)		Drug Costs[9] (934 hospitals)		Total Cost of Care[10] (1016 hospitals)		Length of Stay (1024 hospitals)	
	Slope	p Value	Slope	p Value	Slope	p Value	Slope	p Value
Central clinical pharmacy services								
Drug-use evaluation					-34871	0.001		
In-service education			-1148	0.016				
Drug information	-0.002	0.043	-1090	0.015	-11749402	0.003		
Poison information								
Clinical research	-0.008	0.0001			42922279	0.0001		
Patient-specific clinical pharmacy services								
ADR monitoring					-6599253	0.008		
Pharmacokinetic consultations								
Drug therapy monitoring								
Drug protocol management			-1065	0.049	-17423551	0.001	-1.30	0.008
TPN team participation					10789291	0.001		
Drug counseling								
CPR team participation	-0.002	0.039						
Medical rounds participation					-4770426	0.0001	-1.71	0.001
Admission drug histories	-0.006	0.005	-1450	0.011	-6106570	0.017		
Pharmacy staffing/occupied beds								
All pharmacists	-0.0381	0.0185						
Pharmacy administrators	X[a]	X[a]	46442	0.0001	-324890768	0.0001		
Dispensing pharmacists	X[a]	X[a]	53299	0.0001	120000000	0.006		
Clinical pharmacists	X[a]	X[a]	-21809	0.018	-38864012	0.007	-26.59	0.001
Pharmacy technicians	X[a]	X[a]	54915	0.0001				
R^2 (actual)	22.4%		15.3%		48.9%		11.4%	

[a]Not determined as part of the original analysis. See Table 4 for specific information on pharmacy staffing and mortality rates.

correlation matrix for independent variables and variance inflation factor were used to examine possible effects of multicolinearities for the length of stay analysis.[45] These indicated that there were no apparent problems among the set of independent variables.

We used severity of illness multiple regression analysis to determine interrelationships among mortality rates, drug costs, total cost of care, and length of stay. These relationships are reported as slope, R^2, and significance. Slope measures the rate of change for the variable and is expressed as either positive (e.g., as drug costs increased, total cost of care increased) or negative (e.g., as drug costs increased, mortality rates decreased). A higher slope indicated that changes in that variable were associated with greater changes in the other variable (e.g., changes in the number of clinical pharmacists/occupied bed were associated with greater changes in mortality rates than other pharmacy variables). In addition, multiple regression analysis allowed us to determine direct relationships and associations between clinical pharmacy services and pharmacist staffing variables and mortality rates, drug costs, total cost of care, and length of stay in U.S. hospitals.

A comparison of clinical pharmacy services and pharmacy staffing variables that was statistically significant in the multiple regression model for length of stay was developed further. The difference in the length of stay, based on whether the hospital provided the clinical pharmacy service, was determined. Each pharmacy staffing variable was analyzed in a separate multiple regression model that included mortality rates and the severity of illness variables. The a priori level of significance for all tests was set at 0.05.

Results

Length of Stay

A total of 1024 hospitals (64%) of the 1597 general medical-surgical hospitals from the 1992 NCPS database were matched from the 3444 hospitals from the AHA database (potential pool of study hospitals) for length of stay data. These 1024 hospitals constituted the study population. The mean length of stay for each patient admission was 7.12 ± 14.02 days, 55,586 ± 52,190 patient-days/hospital/year, and

Table 2. Summary of Significant Associations Between Clinical Pharmacy Services and Lower Number of Deaths, Drug Costs, and Total Cost of Care

	Lower Deaths (actual)[8] (1029 hospitals)		Lower Drug Costs ($)[9] (934 hospitals)		Total Cost of Care ($) (increase or reduction)[10] (1016 hospitals)	
	Per Hospital	All Hospitals[a]	Per Hospital	All Hospitals[a]	Per Hospital	All Hospitals[a]
Central clinical pharmacy services						
Drug use evaluation					1,119,810	1,005,589,542
In-service education			77,879	48,518,735		
Drug information	3.89	10,463	430,580	90,852,346	5,226,128	1,212,461,747
Poison information						
Clinical research	11.63	21,125			(9,558,788)[b]	(1,013,231,529)[b]
Patient-specific clinical pharmacy services						
ADR monitoring					1,610,841	1,101,815,258
Pharmacokinetic consultations						
Drug therapy monitoring						
Drug protocol management			137,334	45,045,444	1,729,608	614,010,986
TPN team participation					(3,211,355)[b]	(1,027,633,638)[b]
Drug counseling						
CPR team participation	2.1	5047				
Medical rounds participation					7,979,721	1,212,917,508
Admission drug histories	8.61	3843	213,388	5,548,094	6,964,145	208,924,355

[a]All hospitals that offer the service.
[b]Increase in total costs associated with these services.

57,198,012 patient-days/year for all study hospitals/year (41% of total patient-days for all U.S. hospitals).[53] The mean total cost/patient-day was \$933 ± \$428. The mean number of admissions/year was 8061.39 ± 6721.89 admissions/hospital or 8,254,883[36] total admissions (34% of all admissions). The average daily census (ADC) for study hospitals was 152.32 ± 143.28 patients/day. Study populations (pool of all U.S. hospitals available for analysis from HCFA and AHA)[43, 44] for this and our previous studies represent 3763 hospitals for hospital staffing and mortality rates (78% of all hospitals)[7]; 1029 hospitals for clinical pharmacy services and mortality rates (31% of all hospitals)[8]; 934 hospitals for clinical pharmacy services and drug costs (25% of all hospitals)[9]; 1016 hospitals for clinical pharmacy services, staffing, and total cost of care (30% of all hospitals)[10]; and 1024 hospitals for length of stay (30% of all hospitals).

Table 1 shows associations among mortality rates, drug costs, and total cost of care, length of stay, and clinical pharmacy services and hospital staffing. Two services were associated with reduced length of stay: drug protocol management and pharmacist participation on medical rounds. The number of clinical pharmacists/occupied bed tended to have the greatest association (slope) with reductions in length of stay. The R^2 for the length of stay regression model was 11.4% and the adjusted R^2 was 10.8%. Table 2 presents information on clinical pharmacy services: deaths/hospital and for all hospitals offering the service,[8] drug cost reductions/hospital and for all hospitals offering the service,[9] and total cost of care increases or decreases for each hospital and all hospitals offering the service.[10] Table 3 shows reductions in length of stay for hospitals that have pharmacist-provided drug protocol management and pharmacist participation on medical rounds (from the length of stay multiple regression model). Figure 1 shows the relationship between mean length of stay/hospital and staffing level of clinical pharmacists (graphed as quintiles: tenth, thirtieth, fiftieth, seventieth, and ninetieth percentiles).

Interrelationships among Health Care Outcome Variables

As drug costs/occupied bed increased, severity of illness-adjusted mortality rates decreased (slope -38609852, actual R^2 8.2%, adjusted R^2 7.6%, $p<0.0001$). This relationship is shown graphically in Figure 2 as death rate/1000 admissions and drug costs/occupied bed/year (quintiles). As the total cost of care/occupied bed increased, severity of illness-adjusted

Table 3. Length of Stay for Hospitals with Clinical Pharmacy Services Associated with Significantly Shorter Length of Stay in the Multiple Regression Model

Services Associated with Reduced Length of Stay	No. (%) of Hospitals Providing the Service	Mean Reduction in Length of Stay/Patient in Hospitals Offering the Service	Total No. of Patient Days Reduced/Hospital Offering the Service	Total No. of Patient Days Reduced for All Hospitals Offering the Service
Drug protocol management	354 (34.6)	1.22 ± 0.91	432.67 ± 167.93	152,998.80
Medical rounds participation	153 (14.8)	1.34 ± 0.93	164.82 ± 88.51	25,178.46

Table 4. Relationships between Hospital Pharmacy Staffing and Severity of Illness-Adjusted Mortality Rates

Types of Hospital Pharmacy Staff	Slope	R^2 Actual (%)	R^2 Adjusted (%)	Significance
All pharmacists	-0.101710	4.5	4.1	0.0001
Pharmacy administrators	0.190177	3.4	3.2	0.0001
Dispensing pharmacists	-0.091700	3.6	3.3	0.0001
Clinical pharmacists	-0.408114	10.1	9.8	0.0001
Pharmacy technicians	-0.097564	3.2	2.8	0.0001

mortality rate decreased (slope -5846720642, actual R^2 14.9%, adjusted R^2 14.1%, $p<0.0001$; Figure 3). As drug costs/occupied bed increased, the total cost of care increased (slope 18.989, actual R^2 11.5%, adjusted R^2 10.7%, $p<0.0001$). These were the only statistically significant associations among severity of illness-adjusted mortality rates, drug costs, total cost of care, and length of stay.

Clinical Pharmacy Services, Hospital Pharmacy Staffing, and Mortality Rate, Drug Costs, and Total Cost of Care

Figure 4 (quintiles), taken from published data but not graphed,[8] shows the relationship between number of pharmacists/100 occupied beds and number of deaths/hospital. The difference between the highest number of deaths/hospital (thirtieth percentile) and lowest number of deaths/hospital (ninetieth percentile) was 264 deaths, a 36% reduction from the 729 deaths/hospital in the thirtieth percentile. Table 4 presents severity of illness-adjusted multiple regression data for hospital pharmacy staffing categories. As the number of pharmacy administrators increased, mortality rates increased. As the number of dispensing pharmacists, clinical pharmacists, and technicians increased, mortality rates decreased. The number of clinical pharmacists/occupied bed tended to have the greatest association (slope) with reductions in mortality rates (Figure 5).

The only pharmacy variable that was

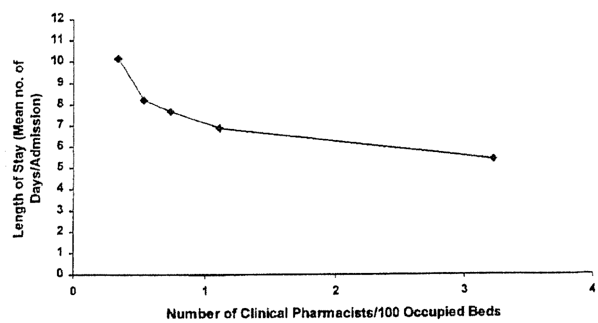


Figure 1. Clinical pharmacist staffing and length of hospital stay.

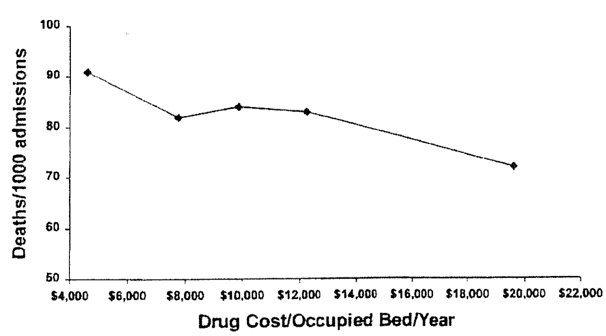


Figure 2. Hospital deaths/1000 admissions and drug costs.

associated with positive outcomes with all four outcome measures was the number of clinical pharmacists/occupied bed. This tended to have the greatest association (slope) with reductions in mortality rate, drug costs, and length of stay. It also had the second highest association (slope) with reductions in total cost of care. No individual clinical pharmacy service was associated with all four outcome measures. Three services were associated with three outcome measures: pharmacist-provided drug information, drug protocol management, and admission drug histories. Pharmacist participation on medical rounds was associated with improvements with two outcome measures, total cost of care and length of stay. Five services were associated with improvements with one outcome measure: drug use review, in-service education, clinical research, ADR monitoring, and CPR team participation. Pharmacist-provided drug information, drug protocol management, and admission drug histories were associated with reductions in both drug costs and total cost of care. Pharmacist-provided clinical research and participation on the TPN team were associated with increased total cost of care.

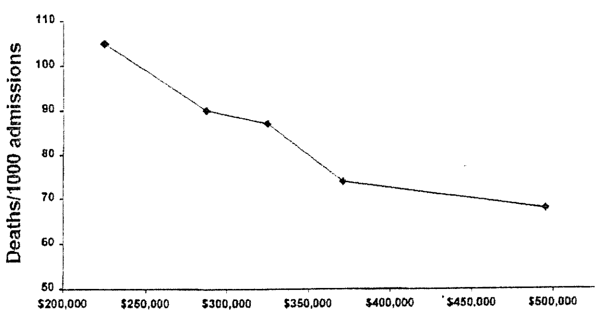


Figure 3. Hospital deaths/1000 admissions and total cost of care.

Discussion

Length of Stay

Reasons why pharmacist-provided drug protocol management was associated with shorter length of stay are unknown. Perhaps the service provides quality control for therapy. Ensuring the quality of drug therapy may increase the efficiency and quality of patient care, which can be measured as shorter length of stay. Length of stay is a strong predicator of hospitals' quality and efficiency of care.[54, 55] Inappropriate drug prescribing is associated with increased length of stay.[23, 24] There were 432.76 fewer patient-days/hospital associated with the presence of pharmacist-provided drug protocol management, a decrease of 152,998.80 patient-days for the 354 hospitals having this service. A potential reduction of 442,572.80 patient-days (1% of total patient-days for all 1024 hospitals) could be realized if all 1024 hospitals had this service. The median pharmacist salary cost/hospital/year for providing drug protocol management was $1650, or $3.81 of pharmacist salary cost/patient-day saved.[56] Every dollar of pharmacist salary cost was associated with a reduction of $244.88 in length of stay savings ($933 cost/day divided by $3.81), or a 1:244.88 ratio. This service was associated with substantial reductions in cost of care and probable increased profitability for hospitals having pharmacists perform drug protocol management. The service was probably an indicator of hospitals' efficiency and quality of care.

Reasons why pharmacists' participation on medical rounds was associated with shorter length of stay also are unknown. Since medical rounds are where most decisions are made about patient care, perhaps pharmacists influence drug

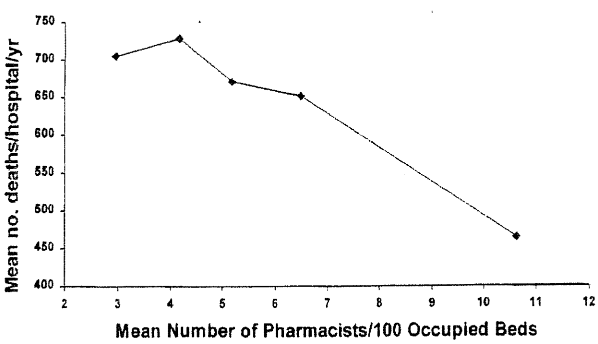


Figure 4. Pharmacist staffing and deaths/hospital.

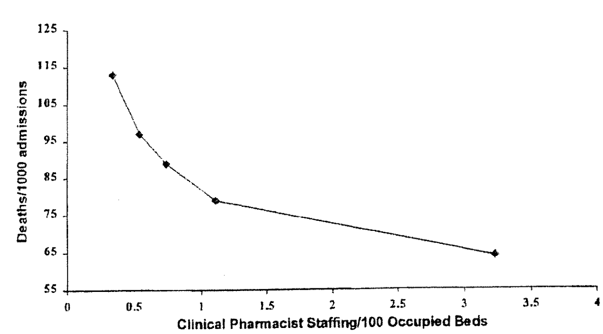


Figure 5. Clinical pharmacist staffing and hospital deaths/1000 admissions.

therapy decisions and reduce risks of adverse drug events. Other investigators also found this result associated with placing clinical pharmacists on rounds in individual hospitals.[26, 27, 57-59] Our data clearly confirm the finding. There were 164.82 fewer patient-days/hospital associated with the presence of pharmacist participation on medical rounds, a decrease of 25,178.46 patient-days in the 153 hospitals having the service. A potential reduction of 168,514.65 patient-days (0.3% of the total patient-days for all 1024 hospitals) could be realized if all 1024 hospitals had this service. The median pharmacist salary cost/hospital for pharmacists attending medical rounds was $31,652/year, or $192.04 of pharmacist salary cost/patient-day saved.[56] Every dollar of pharmacist salary cost was associated with a reduction of $4.86 in length of stay savings ($933 cost/day divided by $192.04), or a 1:4.86 ratio. This service was associated with substantial reductions in cost of care and probable increased profitability for hospitals having pharmacists on medical rounds. It is probably an indicator of hospitals' efficiency and quality of care.

As clinical pharmacist staffing increased from the tenth percentile (0.34/100 occupied beds) to the ninetieth percentile (3.23/100 occupied beds), mean length of stay fell from 10.17 to 5.39 days/patient, a difference of 4.78 days/patient or a 47% reduction. The number of clinical pharmacists/occupied bed tended to have the greatest association (slope) with reductions in length of stay. It was the best predictor of all pharmacy variables for shorter length of stay in study hospitals.

Interrelationships between Health Care Outcome Measures

The relationship between the severity of illness-adjusted death rate/admission and drug costs/occupied bed (slope -38609852, R^2 8.2%, $p<0.0001$) is rather striking. As drug costs increased from the tenth ($4623) to the ninetieth percentile ($19,628)/occupied bed/year, the death rate declined from 91/1000 to 72/1000 admissions, a 21% decline. With 8061.39 ± 6721.89 admissions/hospital/year, this translates into a difference of 153 deaths/hospital having drug spending between the tenth and ninetieth percentiles. This translates into a reduction of 0.42 deaths/day/hospital between these drug cost levels. If these differences in deaths were extrapolated to all study hospitals, the number of lives saved associated with increased drug costs could be substantial. The drug cost/death difference between hospitals spending at the tenth and ninetieth percentiles was $14,938/death ($15,005 difference in drug costs/occupied bed/year {tenth–ninetieth percentiles} divided by 153 deaths x 152.32 {ADC}). Since mortality rates are a very good indicator of the quality of care,[3, 4, 42, 48, 49] it appears that higher drug costs predict better patient care.

Reasons for findings between drug costs and mortality rates are not known. The relationship between higher drug costs and lower mortality rates suggests that newer more costly drugs may be better than older less expensive ones in reducing deaths. This is not to suggest that indiscriminate use of drugs is appropriate, but health care outcomes must be considered and measured when cost cutting is pursued. This finding suggests that restricting or rationing drugs based on cost alone may be detrimental to patient care. These data clearly indicate that costs and outcomes are associated in a manner that is somewhat unexpected. In the future, pharmacists must focus not only on costs, but also on health care outcome measures. Otherwise, in an effort to reduce costs, we may adversely affect an important health outcome and harm patients.

The relationship between the severity of illness-adjusted death rate/admission and total cost of care/occupied bed (slope -5846720642, R^2 14.9%, $p<0.0001$) is impressive. As total costs increased from the tenth ($287,205) to the ninetieth percentile ($495,305)/occupied bed/year, the death rate declined from 105/1000 to 68/1000 admissions (35% decline). With 8061.39 ± 6721.89 admissions/hospital/year, this translates into a difference of 298 deaths/hospital having total spending between the tenth and ninetieth percentiles. This translates into a reduction of 0.82 deaths/day/hospital between these total cost of care levels. If these differences in deaths were extrapolated to all study hospitals, the number of lives saved associated with increased total cost of care could be substantial. The total cost/death difference between hospitals spending at the tenth and ninetieth percentiles was $106,368/death ($208,100 difference in total costs/occupied bed/year {tenth–ninetieth percentile} divided by 298 deaths x 152.32 {ADC}). Since mortality rates are a very good indicator of quality of care,[3, 4, 42, 48, 49] it appears that higher hospital costs predict better patient care. This suggests that indiscriminate cost cutting in the hospital (staff or supplies) may be deleterious to patient care.

Reasons for findings between total cost of care and mortality rates are unknown. This relationship is not unexpected, since the largest component of a hospital's cost structure is personnel, and increased staffing levels of medical residents, registered nurses, pharmacists, medical technologists, and total hospital personnel are associated with lower mortality rates.[7] The relationship between drug costs and total cost of care (slope 18.99, R^2 11.5%, $p<0.0001$) seems logical, since drug costs are a component of total hospital costs.

Clinical Pharmacy Services, Hospital Pharmacy Staffing, and Mortality Rates, Drug Costs, and Total Cost of Care

Discussion regarding mortality rates, drug costs, total cost of care, and clinical pharmacy services and hospital pharmacy staffing variables are available elsewhere.[7-10] Relationships between the severity of illness-adjusted death rate/admission and clinical pharmacist staffing/occupied bed (slope -0.408114, R^2 10.1%, $p<0.0001$) are striking. As clinical pharmacist staffing levels increased from the tenth (0.34/100 occupied beds) to the ninetieth percentile (3.23/100 occupied beds), hospital deaths declined from 113/1000 to 64/1000 admissions (43% decline). With 8061.39 ± 6721.89 admissions/hospital/year, this translates into a difference of 395 deaths/hospital having clinical pharmacist staffing between the tenth and ninetieth percentiles. This translates into a reduction of 1.09 deaths/day/hospital between these staffing levels. If these differences in deaths were extrapolated to all study hospitals, the number of lives saved associated with increased clinical pharmacist staffing could be substantial. The clinical pharmacist staffing/100 occupied beds/death difference between hospitals staffing clinical pharmacists at the tenth and ninetieth percentiles was 0.0073 FTE clinical pharmacist/death (2.89 FTE clinical pharmacist {tenth–ninetieth percentile} divided by 395 deaths). The 1992 mean pharmacist salary for hospital pharmacists was $43,791 ± 12,206.[56] The total pharmacist salary cost/death difference between hospitals having clinical pharmacist staffing at the tenth and ninetieth percentiles was $320 ($43,791 ± 12,206 x 0.0073). Since mortality rates are a very good indicator of quality of care,[3, 4, 42, 48, 49] it appears that higher staffing levels of clinical pharmacists predict better patient care.

One of the more disturbing aspects of associations between hospital pharmacy staffing and severity of illness-adjusted mortality rates is the increased death rate associated with increased staffing of hospital pharmacy administrators. This is consistent with what we reported previously with hospital administrators.[7] Given the administrative inefficiency of our health care system,[60] high hospital administrative costs (accounting for 26% of total hospital costs),[61] and this association with mortality rates, it may be prudent to limit the number of hospital pharmacy administrative personnel. In addition, further study seems warranted to determine specific reasons why increased staffing levels of hospital administrators and hospital pharmacy administrators are associated with increased mortality.

With the exception of clinical pharmacists, staffing levels of pharmacy administrators, dispensing pharmacists, and pharmacy technicians have both positive and negative associations with health care outcome measures. Increased hospital pharmacy administrative staffing was associated with increased mortality rates and increased drug costs, but decreased total cost of care. Increased dispensing pharmacist staffing was associated with reduced mortality rates, but increased drug costs and increased total cost of care. Increased pharmacy technician staffing was associated with decreased mortality rates, but increased drug costs. In contrast, increased clinical pharmacist staffing was uniformly associated with reduced mortality rates, decreased drug costs, decreased total cost of care, and shorter length of stay. If we are to effect major health care outcome measures and reduce costs, it appears that we should significantly increase clinical pharmacist staffing and reduce pharmacy administrator and dispensing pharmacist staffing. This recommendation takes on added importance considering that only 11% of pharmacy staffing in 1992 was allocated to clinical pharmacists.[62] We believe the results of our previous studies[7-10] and this study are conclusive with respect to hospital pharmacy staffing. The path is clear, and the profession should not continue to spend most of its personnel resources on the distribution system and administrative personnel. A paradigm shift must occur in organized pharmacy if we are to improve health care outcomes and maximize our ability to reduce health care costs.

The beneficial results of clinical pharmacists and clinical pharmacy services are unequivocal given the data presented. These findings are remarkable since they were evident about 25 years after the first clinical pharmacists began to appear in the nation's hospitals. It is clear that clinical pharmacists are associated with improvements in the study's four outcome measures. It is less clear what specific clinical pharmacy services conclusively produce benefits with all of these health care outcomes. This is not surprising, since clinical pharmacists have been practicing only for a little over 3 decades. Clinical pharmacy is now in a phase where services are still being solidified. Standard practice methodology is not fully accepted or available in many hospitals. It may take another generation before specific clinical pharmacy services are common expectations of care in the nation's hospitals. Although the journey is not completed, we are well along the road to improving patient care. The results of our five studies unequivocally show that pharmacists, by providing clinical pharmacy services, have a bright future in health care. To make optimum contributions, we must leave the dispensing and administrative modes and provide direct patient care. It is our hope that pharmacists use these data to complete the work that the first clinical pharmacists began in the 1960s and 1970s.

Specific Recommendations

Hospital Pharmacy Staffing

Data from our five studies unequivocally show that the best way for the profession to improve patient care and reduce costs is to increase staffing levels of clinical pharmacists. Given the mixed results with hospital pharmacy administrators and dispensing pharmacists, staffing levels for these types of pharmacists should be decreased. Priority should be given to reducing pharmacists' dispensing and administrative time and increasing the level of clinical services provided to patients.

Clinical Pharmacy Services

Strong consideration should be given to having drug histories, drug information, and drug protocol management services as part of core clinical pharmacy services for most hospitals. These services were associated with positive outcomes with three of the four health care outcome measures. Including medical rounds into the service core mix may be considered since this service was associated with improvements with two health care outcome measures. No clear picture emerges on the remaining clinical pharmacy services. However, regardless of services provided, staffing of clinical pharmacists was the best indicator of improved patient care outcomes and reduced costs. Given staffing levels for pharmacy in U.S. hospitals, it is likely that specific populations of patients must be identified to receive clinical pharmacy services.[62]

Cost Savings

Given the relationship between drug costs, total cost of care, and mortality rates, it seems prudent to suggest that cost-cutting initiatives should include appropriate health care outcome variables (mortality rates, length of stays, etc.). If we do not include these measures when implementing initiatives, we ultimately may decrease the quality of care and harm patients. Any measures that cut costs should have an appropriate monitoring period that includes assessment of both costs and patient care outcomes. These results clearly show that reduced drug costs and reduced total cost of care can affect patients in a negative way. We must remember that the guiding principle of patient care is first to do no harm.

Limitations

Mortality rates, drug costs, total cost of care, and length of stay information is from 1992 and does not reflect the current year. Annual inflation rates and annual drug cost inflation rates of 20% would have to be considered to interpret these dollar figures in terms of current costs.[62] Similarly, the data do not reflect changes that have occurred in the health care delivery and reimbursement system since 1992. It is possible that information provided to the AHA by hospitals and provided to us for the NCPS database were inaccurate. We did not attempt to verify the information. The total variance explained by our five regression models was consistent with other studies.[2–4, 50, 63, 64] Since these studies were among the first to compare clinical pharmacy services, pharmacist staffing, and major health care outcome measures in a large number of U.S. hospitals, the findings have to be replicated in future studies. It is possible that the hospitals in our study population were not representative of all U.S. hospitals. However, this is doubtful because they represent 25–78% of all hospitals[7-10] available from HCFA and the AHA for possible study.[43, 44] This study design allowed us to determine direct relationships between variables, but it did not allow us to determine causality. We were able to obtain only information about clinical pharmacy services. Information about services of other health care professionals, hospital structure, process, or other variables that could affect these outcome measures could not be obtained or evaluated. If these data were available, it is possible that they could affect our findings. Therefore, these findings should not be construed as cause and effect. Caution should be employed in applying our findings to individual hospitals.

Summary

These five studies clearly support the role of clinical pharmacists and clinical pharmacy services in caring for patients in the nation's hospitals. Increased staffing levels of clinical pharmacists were associated with improvements in all four heath care outcome measures. The number of clinical pharmacists/occupied bed tended to have the greatest association with reductions in mortality rate, drug costs, and length of stay. Given positive and negative findings with hospital pharmacy administrator and dispensing pharmacist staffing and outcome measures, it appears that the best way to improve patient care and reduce costs is to increase staffing levels of clinical pharmacists and promote clinical pharmacy services that these pharmacists perform. Seventeen clinical pharmacy services were associated with improvements in mortality rates, drug costs, total cost of care, and length of stay in U.S. hospitals. It is our hope that pharmacists use the results of these five studies to continue the development of clinical pharmacy. We must establish a common set of services to provide to patients.

Appendix 1. Definitions of Clinical Pharmacy Services

Central Clinical Pharmacy Services

- Drug use evaluation: check if at minimum drug use patterns are analyzed and results are reported to hospital committee.
- In-service education: pharmacist presents continuing education to fellow employees (M.D., R.N., R.Ph., etc.) on a scheduled basis at least 4 times/year.
- Drug information: provided only if a formal drug information service with specifically assigned pharmacist(s) is available for questions. Does not require a physical location called drug information center.
- Poison information: provided only if a pharmacist is available to answer toxicity and overdose questions on a routine basis with appropriate resources.
- Clinical research: performed by pharmacists either as a principal investigator or coinvestigator, or pharmacist is likely to be (co)author of a published paper. Do not check if activity is limited to investigational drug distribution or record keeping.

Patient-Specific Clinical Pharmacy Services

- ADR management: pharmacist evaluates potential adverse drug reaction while the patient is hospitalized and appropriately follows through with physicians.
- Pharmacokinetic consultation: provided only if at a minimum the drug regimen, serum levels, and patient's medical record are reviewed and verbal or written follow-up is provided when necessary.
- Drug therapy monitoring: provided only if a patient's medical record is reviewed and verbal or written follow-up is provided when necessary. Monitoring is continuing and repeated, often on daily basis. Do not check if only drug orders are reviewed. Does not include pharmacokinetic consults, TPN team, rounds, ADR management, or drug therapy protocol management.
- Drug protocol management: pharmacist, under the order of a prescriber, requests laboratory tests as necessary and initiates or adjusts drug dosage to obtain the desired therapeutic outcome (e.g., aminoglycoside or heparin dosing per pharmacy).
- TPN team participation: pharmacist at a minimum reviews medical records and/or provides written or verbal follow-up if required.
- Drug counseling: pharmacist provides counseling on drugs either during hospitalizations or at discharge. Do not check if counseling involves solely review of label directions.
- CPR team participation: pharmacist is an active member of the CPR team, attending most arrests when present in the hospital.
- Medical rounds participation: pharmacist rounds with medical team at least 3 days/week actively providing specific input.
- Admission drug histories: pharmacist provides admission histories.

References

1. Kuhn EM, Hartz AJ, Gottlieb MS, Rimm AA. The relationship of hospital characteristics and results of peer review in six large hospitals. Med Care 1991;29:1028–38.
2. Green J, Passman LJ, Wintfield N. Analyzing hospital mortality—the consequences of diversity in patient mix. JAMA 1991;265:1849–53.
3. Hartz AJ, Gottlieb M, Kuhn EM, Rimm A. A national validation study of Medicare mortality studies (project #1247-M). Technical report to the Health Standards Review Bureau. Washington, DC: U.S. Government Printing Office, 1989.
4. Hartz AJ, Krakauer H, Kuhn EM, et al. Hospital characteristics and mortality rates. N Engl J Med 1989:321:1720–5.
5. Kelly JV, Hellinger FJ. Physician and hospital factors associated with mortality in surgical patients. Med Care 1986;24:785–800.
6. Pitterle ME, Bond CA, Raehl CL, Franke T. Hospital and pharmacy characteristics associated with mortality rates in United States hospitals. Pharmacotherapy 1994;14(5):620–30.
7. Bond CA, Raehl CL, Pitterle ME, Franke T. Health care professional staffing, hospital characteristics, and hospital mortality rates. Pharmacotherapy 1999;19(2):130–8.
8. Bond CA, Raehl CL, Franke T. Clinical pharmacy services and hospital mortality rates. Pharmacotherapy 1999;19(5):767–81.
9. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacist staffing, and drug costs in United States hospitals. Pharmacotherapy 1999:19(12)1354–62.
10. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacy staffing, and the total cost of care in United States hospitals. Pharmacotherapy 2000:20(6);609–21.
11. Black BL. Resource book on progressive pharmaceutical services. Bethesda, MD: American Society of Hospital Pharmacists, 1986.
12. Hatoum HT, Catizone C, Hutchinson RA, et al. An eleven-year review of the pharmacy literature: documentation of the value and acceptance of clinical pharmacy. Drug Intell Clin Pharm 1986;20:33–48.
13. Comptroller General of the United States. Study of health facilities construction costs. Washington, DC: U.S. Government Printing Office. 1972:68–72, 363–79.
14. Barker KN, Pearson RE. Medication distribution systems. In: Brown TR, Smith, MC, eds. Handbook of institutional pharmacy practice. Baltimore: Williams & Wilkins, 1986:325–51.
15. Elenbaas RM, Payne VW, Bauman JL. Influence of clinical pharmacists consultations on the use of blood level test. Am J Hosp Pharm 1980;37:61–4.
16. Bollish SJ, Kelly WN, Miller DE, et al. Establishing an aminoglycoside pharmacokinetic monitoring service in a community hospital. Am J Hosp Pharm 1981;38:73–6.
17. Abramowitz PA, Nold EC, Hatfield SM. Use of clinical pharmacists to reduce cefamandole, cefoxitin, and ticarcillin costs. Am J Hosp Pharm 1982;39:1176–80.
18. Mutchie KD, Smith KA, MacKay MW, et al. Pharmacists' monitoring of parenteral nutrition: clinical and cost effectiveness. Am J Hosp Pharm 1979;36:785–7.
19. Covinsky JO, Hamburger SC, Kelly KL, et al. Impact of docent clinical pharmacists on treatment of streptococcal pneumonia. Drug Intell Clin Pharm 1982;16:587–91.
20. Bond CA, Salinger RJ. Fluphenazine out-patient clinics: a pharmacist's role. J Clin Psychiatry 1979;40:501–3.
21. Herfindal ET, Bernstein LR, Kishi DT. Effect of clinical pharmacy services on prescribing on an orthopedic unit. Am J Hosp Pharm 1983:40:1945–51.
22. Avorn J, Soumerai SB. Improving drug-therapy decisions through educational outreach: a randomized controlled trial of academically based "detailing." N Engl J Med. 1983;308:1457–63.
23. Knapp DE, Knapp DA, Speedie MK, et al. Relationship of inappropriate drug prescribing to increased length of hospital stay. Am J Hosp Pharm 1979;36:1334–7.
24. Knapp DE, Speedie MK, Yaeger DM, et al. Drug prescribing and its relationship to length of hospital stay. Inquiry 1980;17:254–9.
25. McKenney JM, Wasserman AH. Effect of advanced pharmaceutical services on the incidence of adverse drug reactions. Am J Hosp Pharm 1979:36:1691–7.
26. Clapham CE, Hepler CE, Reinders TP, et al. Economic consequences of two drug-use control systems in a teaching hospital. Am J Hosp Pharm 1988:45:2329–40.
27. Bjornson DC, Hiner WO, Potyk RP, et al. Effect of pharmacist on health care outcomes in hospitalized patients. Am J Hosp Pharm 1993;50:1875–84.
28. Jenkins MH, Bond CA. The impact of clinical pharmacists on psychiatric patients. Pharmacotherapy 1996;16(4):708–14.
29. Monson RA, Bond CA, Schuna A. Role of the clinical pharmacist in improving out-patient drug therapy. Arch Intern Med 1981;141:1441–4.
30. Bond CA, Monson R. Sustained improvement in drug documentation, compliance, and disease control—a four year ambulatory care model. Arch Intern Med 1984;144:1159–62.
31. Tang I, Vrahnos D, Hatoum H, et al. Effectiveness of clinical pharmacist interventions in a hemodialysis unit. Clin Ther 1993:15:459–64.
32. Brown WJ. Pharmacist participation on a multidisciplinary rehabilitation team. Am J Hosp Pharm 1994;51:91–2.
33. Garber AM, Fuchs VR, Silverman JF. Case mix, costs, and outcomes between faculty and community services in a university hospital. N Engl J Med 1984;310:1231–7.
34. Pauly MV, Wilson P. Hospital output forecasts and the cost of empty hospital beds. Health Serv Res 1986;21:413–28.
35. Rich EC, Gifford G, Luxenberg M, et al. The relationship of hospital staff experiences to the cost and quality of inpatient care. JAMA 1990:263:953–7.
36. Watts CA, Klastorin TD. The impact of case-mix on hospital costs: a comparative analysis. Inquiry 1990:17:357–67.
37. Schumock GT, Meek PD, Ploetz PA, Vermeulen LC. Economic evaluation of clinical pharmacy services—1988–1995. Pharmacotherapy 1996;16(6):1188–1208.
38. Gattis WA, Hasselblad V, Whellan DJ, O'Connor CM. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure team. Arch Intern Med 1999;159:1939–45.
39. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. JAMA 1999;282:267–70.
40. Bond CA, Raehl CL, Pitterle ME. 1992 National clinical pharmacy services study. Pharmacotherapy 1994;14(3): 282–304.
41. Raehl CL, Bond CA, Pitterle ME. Hospital pharmacy services in the Great Lakes region. Am J Hosp Pharm 1990;47: 1283–1303.
42. Raehl CL, Bond CA, Pitterle ME. Pharmaceutical services in U.S. hospitals in 1989. Am J Hosp Pharm 1992;49:323–46.
43. Health Care Financing Administration. Medicare hospital mortality information (on data tape). Washington, DC: Health Care Financing Association, 1992.
44. American Hospital Association. American Hospital Association abridged guide to the health care field (on diskettes). Chicago, IL: Author, 1992.
45. SAS Institute Inc. SAS, version 6.12. Cary, NC: Author, 1998.
46. Keeler EB, Rubenstein LV, Kahn KL, et al. Hospital characteristics and quality of care. JAMA 1992;268:1709–14.
47. Shortell SM, Hughes EFX. The effect of regulation, competition, and ownership on mortality rates among hospital inpatients. N Engl J Med 1988;318:1100–7.
48. Dubois RW, Brooks RH, Rodgers WH. Adjusted hospital death rates; a potential screen for quality of medical care. Am J Public Health 1987;77:1162–7.
49. Krakauer H, Bailey RC, Skellan KJ, Stewart JD, Hartz AJ. Evaluation of the HCFA model for the analysis of mortality following hospitalization. Health Serv Res 1992:27(3):317–35.
50. Green J, Wintfield N, Sharkey P, Passman LJ. The importance of severity of illness measures in assessing hospital mortality. JAMA 1990;262:241–6.
51. Wampole BE, Freund RD. Use of multiple regression in

counseling psychology research: a flexible data analytic strategy. J Counsel Psychol 1987;34:372–82.
52. **Pedhazur EJ.** Multiple regression in behavioral research: explanation and prediction, 2nd ed. New York: Harcourt Brace Jovanovich, 1982.
53. **American Hospital Association.** Hospital statistics, 1992, Chicago: Author, 1993.
54. **Anonymous.** Use of LOS by professional standards review organizations (PSRO) is an important illustration. Fed Register 1979;44(108):32,081–91.
55. **Goran M.** Evolution of the PSRO hospital review system. Med Care 1979;17(5 suppl):1–18.
56. **Bond CA, Raehl CL, Pitterle ME.** Cost of pharmaceutical services in U.S. hospitals in 1992. Am J Hosp Pharm 1995;52:503–613.
57. **Mamdani MM, McCreadie RE, Simmerman C, et al.** Clinical and economic effectiveness of an inpatient anticoagulation service. Pharmacotherapy 1999;19(9):1064–74.
58. **Boyko WL, Yurkowski JJ, Ivey MF, et al.** Pharmacist influence on economic outcomes in a tertiary care teaching hospital. Am J Health-Syst Pharm 1997;54:1591–5.
59. **Haig GM, Kiser LA.** Effect of pharmacist participation on a medical team on costs, charges, and length of stay. Am J Hosp Pharm 1991;48:1457–62.
60. **Woolhandler S, Himmelstein DV.** The deteriorating administrative efficiency of the United States health care system. N Engl J Med 1991;324:1253–8.
61. **Woolhandler S, Himmelstein DV.** Costs of care and administration at for-profit and other hospital in the United States. N Engl J Med 1997;336:769–74.
62. **Bond CA, Raehl CL.** Changes in pharmacy, nursing, and total personnel staffing in United States hospitals: 1989–1998. Am J Health-Syst Pharm 2000;57:970–4.
63. **Shortell SM, Hughes EFX.** The effect of regulation, competition, and ownership on mortality rates among hospital inpatients. N Engl J Med 1988;318:1100–7.
64. **Daley J, Jencks S, Draper D, et al.** Predicting hospital-associated mortality for Medicare patients. JAMA 1988;260:3617–14.

Attachment 3

Special Article

Medication Errors in United States Hospitals

C. A. Bond, Pharm.D., FASHP, FCCP, Cynthia L. Raehl, Pharm.D., FASHP, FCCP, and Todd Franke, Ph.D.

This study evaluated hospital demographics, staffing, pharmacy variables, health care outcomes measures (severity of illness-adjusted mortality rates, drug costs, total cost of care, and length of stay) and medication errors. A database was constructed from the 1992 American Hospital Association's Abridged Guide to the Health Care Field, the 1992 National Clinical Pharmacy Services database, and 1992 mortality data from the Health Care Financing Administration. Simple statistical tests and a severity of illness-adjusted multiple regression analysis were employed. The study population consisted of 1116 hospitals that reported information on medication errors and 913 hospitals that reported information on medication errors that adversely affected patient care outcomes. We evaluated factors associated with the 430,586 medication errors and 17,338 medication errors that adversely affected patient care outcomes. Medication errors occurred in 5.07% of the patients admitted each year to these hospitals. Each hospital experienced a medication error every 22.7 hours (every 19.73 admissions). Medication errors that adversely affected patient care outcomes occurred in 0.25% of all patients admitted to these hospitals/year. Each hospital experienced a medication error that adversely affected patient care outcomes every 19.23 days (or every 401 admissions). The following factors were associated with increased medication errors/occupied bed/year: lack of pharmacy teaching affiliation (slope = 0.8875, $p=0.0416$), centralized pharmacists (slope = 1.0942, $p=0.0001$), number of registered nurses/occupied bed (slope = 1.624, $p=0.032$), number of registered pharmacists/occupied bed (slope = 25.0573, $p=0.0001$), hospital mortality rate (slope = 2.8017, $p=0.0192$), and total cost of care/occupied bed/year (slope = 0.01432, $p=0.0091$). Factors associated with decreased medication errors were location in the Mid-Atlantic census region (slope = -1.5182, $p=0.03$), affiliation with a pharmacy teaching program (slope = -1.0252, $p=0.0349$), decentralized pharmacists (slope = -0.9843, $p=0.0037$), and number of medical residents/occupied bed (slope = -1.478, $p=0.0014$). There was a 45% decrease in medication errors (1.81-fold decrease) in hospitals that had decentralized pharmacists, compared with hospitals that had centralized pharmacists. In addition, there was a 94% decrease in medication errors that adversely affected patient care outcomes (16.88-fold decrease) in hospitals that had decentralized pharmacists compared with hospitals that had only centralized pharmacists. Based on previous field studies and our findings in 1116 hospitals, it appears that one of the most effective ways to prevent or reduce medication errors is to decentralize pharmacists to patient care areas. The results of this study should help hospitals reduce the number of medication errors that occur each year.

(Pharmacotherapy 2001;21(9):1023–1036)

The Institute of Medicine's 1999 report suggested that medical errors accounted for 44,000–98,000 deaths each year.[1-3] These deaths exceed the eighth leading cause of death in the United States.[4] It is estimated that the total cost of medical errors is $17 billion–$29 billion annually.[5, 6] Although the percentage of drug-related medical errors in ambulatory settings is unknown, drugs are the most common cause of medical errors in hospitals, affecting 3.7% of patients.[2, 3] Clearly, medication errors are a significant component of medical errors in U.S. hospitals.

Hospital medication errors occur in 3–6.9% of inpatients.[2, 7-10] The error rate for inpatient medication orders was reported to be 0.03–16.9%.[8, 11-13] One analysis determined that 11% of medication errors in hospitals were pharmacy dispensing errors related to the wrong drug or strength.[9] Whereas medication-related errors occur frequently in hospitals, many of these errors apparently do not result in patient harm.[1] In a 1999 report on hospital medication errors compiled by the United States Pharmacopeia, only 3% of 6224 medication errors caused patient harm.[14] Although the frequency of medication errors has been documented, there has been little study of the factors associated with the root causes of these errors.[15]

Unfortunately, nearly all studies of medication errors involved a small number of sites (hospitals or pharmacies) or a limited number of patients. Little is known about what factors might be associated with medication errors in a large population of hospitals. More studies assessing the risk of medication errors are needed to determine the best methods for reducing these errors. This study employed a population-based approach to assess factors associated with the reporting of medication errors in U.S. hospitals.

We tested the associations and correlations between hospital demographics, staffing, and pharmacy variables with the number of medication errors reported in U.S. hospitals. In addition, we determined the correlation between the number of medication errors and four major health care outcome measures: severity of illness-adjusted mortality rates, drug costs, total cost of care, and length of stay. This is the first study to evaluate factors associated with medication errors in a large number of hospitals.

From the Department of Pharmacy Practice, School of Pharmacy, Texas Tech University Health Sciences Center–Amarillo, Amarillo, Texas (Drs. Bond and Raehl); and the School of Public Policy and Social Research, University of California at Los Angeles, Los Angeles, California (Dr. Franke).

Address reprint requests to C. A. Bond, Pharm.D., Department of Pharmacy Practice, School of Pharmacy, Texas Tech University Health Sciences Center–Amarillo, 1300 South Coulter Street, Amarillo, TX 79106; e-mail: cbond@cortex.ama.ttuhsc.edu.

Methods

Hospital medication error information was collected as part of the 1992 National Clinical Pharmacy Services database survey.[16] Pharmacy directors were asked whether their hospital had a medication error reporting system, defined as an ongoing systematic program for reporting, monitoring, and reviewing medication errors. In addition, each pharmacy director was asked to report the total number of medication errors for the previous 12 months and the number of medication errors determined to adversely affect patient outcomes (defined as requiring additional drug therapy, increasing length of stay, or causing permanent harm or patient death). The variables used in this study to compare and contrast medication error data previously were shown to be associated with heath care outcomes and the provision of pharmaceutical services.[16-34]

Sources of Data

Data for pharmacy teaching affiliation, pharmacy directors' degree, pharmacists' location within each hospital, and drug costs were obtained from the 1992 database of the National Clinical Pharmacy Services.[16, 33, 34] The methods used for data analysis previously were published.[16, 33, 34] Mortality rate information was obtained from the Health Care Financing Administration.[35] Data on census region information, size, hospital ownership, hospital staffing, admissions data, occupancy rates, teaching affiliation, length of stay, and total cost of care for each hospital were obtained from the American Hospital Association's (AHA) Abridged Guide to the Health Care Field.[36] The survey instrument of the National Clinical Pharmacy Services was updated and pretested by 25 directors of pharmacy.[16, 33, 34] The questionnaire was mailed to the director of pharmacy in each acute care, general-medical, surgical hospital listed in the AHA database.[36] The methodology, variables, and demographic results of this study were previously published.[16, 33, 34]

The National Clinical Pharmacy Services database is the largest hospital and clinical pharmacy database in the U.S. This information was integrated into one database, and Stata Version 7, implemented on a personal computer (Pentium 450Mz), was used for all statistical analysis.[37] Only inpatient data were analyzed. Respondents from 1116 of the 1597 hospitals identified in the 1992 National Clinical Pharmacy Services database[16] provided information on the number of medication errors at their institutions. These hospitals constituted the study population.

Definitions and subsequent groupings used in the analysis are provided in the appendix. Data analysis was based on grouping hospitals by seven factors associated with health care outcomes and the provision of clinical pharmacy services.[16-34] Hospitals were assigned to one of nine geographic regions defined by the U.S. Bureau of the Census and to one of three size categories. Hospital pharmacy teaching affiliation was identified (affiliation with a college of pharmacy, no college of pharmacy affiliation but an affiliation with other health education programs, or no affiliation with any health education program). Hospital teaching affiliation was defined as teaching or nonteaching, with teaching determined by membership in the Council of Teaching Hospitals or the American Osteopathic Teaching Hospital Association. The pharmacy directors' educational backgrounds were grouped into four categories. Hospital ownership was grouped into four categories. Pharmacists' predominant location within the hospital was grouped into three categories: centralized, decentralized, centralized with ward visits.

Personnel variables used from the AHA database included the number of administrators, physicians, medical residents, registered nurses, licensed practical/vocational nurses, physician assistants, registered pharmacists, medical technologists, dietitians, occupational therapists, physical therapists, respiratory therapists, social workers, and total hospital personnel. In addition, several ratios were employed: ratio of board-certified physicians to all physicians, ratio of registered nurses to licensed practical/vocational nurses, and ratio of registered pharmacists to pharmacy technicians. Only full-time personnel were included in this analysis, since this was the only personnel measure common to the 14 personnel categories in the AHA database.[36] Each personnel variable was divided by the mean number of occupied beds for that hospital, to provide a hospital-specific staffing level based on a common workload measure (staffing/occupied bed). Simple regression was used to analyze staffing, staffing ratio variables, and medication errors.

Multiple regression analysis between the number of medication errors and mortality rates, drug costs/occupied bed/year, total cost of care/occupied bed/year, and mean length of stay were adjusted for severity of illness, which is known to influence these variables. Severity of illness was controlled by forcing three variables into the multiple regression analysis model: percentage of intensive care unit (ICU) days (calculated as ICU days divided by total inpatient days), annual number of emergency room visits divided by the average daily census, and percentage of Medicaid patients (calculated as Medicaid discharges divided by total discharges). These variables previously were validated as severity of illness measures in similar types of studies.[17-22, 25, 26, 38, 39] These specific variables were chosen because they are the only variables validated as adjusters for severity of illness using these national databases.[17-22, 25, 26, 38, 39] Whereas other variables (e.g., APACHE [Acute Physiology and Chronic Health Evaluation] scores, specific patient case mix, patient age, number of surgical patients, physician experience, length of shifts, or patient workloads) have been used to adjust for severity of illness with smaller patient populations, these variables were not available for the study hospitals. Diagnosis-related groups are not reliable severity of illness-adjusters, since many hospitals have inflated these measures.

Patient care outcome measures must adjust for patient characteristics that influence the outcome measure.[39-41] If outcome measures (e.g., mortality rate) do not adjust for severity of illness, conclusions for hospitals that treat more severely ill patients will be inaccurate.

Finally, a multiple regression analysis adjusted for severity of illness was employed with the hospital demographic variables, pharmacy and staffing variables, and health care outcome variables (mortality rate, drug costs, total cost of care, and length of stay). This multiple regression analysis is the most important of our analysis models, as it adjusted for severity of illness and considered the collective effects of demographic, pharmacy, staffing, and health care outcome variables on medication errors.

Statistical Analysis

All multiple regression models used a severity of illness-adjusted model. The severity of illness

Table 1. Geographic Regions and the Number of Medication Errors Reported/Occupied Bed/Year

Region	No. of Hospitals	Medication Errors	Medication Errors that Adversely Affect Patient Care Outcomes
New England	53	2.95 ± 4.35	0.09 ± 0.13
Mid-Atlantic	128	1.32 ± 1.87	0.05 ± 0.10
South Atlantic	136	2.03 ± 2.39	0.10 ± 0.20
East North Central	209	2.69 ± 2.65	0.15 ± 0.36
East South Central	88	2.18 ± 2.18	0.20 ± 0.33
West North Central	106	3.25 ± 2.73	0.14 ± 0.29
West South Central	115	3.07 ± 5.09	0.15 ± 0.26
Mountain	48	3.38 ± 2.56	0.24 ± 0.37
Pacific	136	3.06 ± 10.94	0.09 ± 0.26
Significance		$F(8, 1010) = 2.00$, $p=0.0442$	$F(8, 832) = 3.10$, $p=0.0019$

variables were forced into the multiple regression model before any other variables were allowed to enter. Stepwise procedures were used to select the remaining variables for the model.[42–44]

The variables selected through this method were confirmed by the use of both forward and backward regression techniques. Both techniques selected the same set of variables. The slope measures the rate of change for the variable and is expressed as either positive (e.g., as the medication error rate increased, the mortality rate increased) or negative (e.g., as the number of medical residents/occupied bed increased, the medication error rate decreased). A high slope indicates that changes in the specified variable were associated with significant changes in the other variable (e.g., decentralized location of pharmacists). The multiple regression analysis allowed us to determine the direct relationships and associations between medication errors and mortality rates, drug costs, total cost of care, and length of stay. We also determined the direct relationships and associations between medication errors and hospital demographic, pharmacy, staffing, and health care outcome variables.

Statistical analysis was employed for both the total number of medication errors and the number of medication errors that adversely affected patient outcomes/hospital. Statistical tests employed were the *t* test, analysis of variance (ANOVA), simple regression, and multiple regression. The a priori level of significance for all tests was 0.05.

Results

A total of 1336 hospitals (84%) of the 1597 general-medical, surgical hospitals from the 1992 National Clinical Pharmacy Services database reported having a medication error reporting system in place. The AHA database identified 3444 hospitals that could have been included in the survey; of these, 46% (1597) responded.[36] A total of 1116 hospitals provided specific information on the number of medication errors. Information on the number of medication errors that adversely affected patient care outcomes was reported by 913 hospitals. The 1116 hospitals (70% of the 1597 hospitals) constituted the study population. Hospitals that reported total medication errors and those that reported medication errors adversely affecting patient care outcomes correspond to the useable response rates of 32% and 27%, respectively (1116/3444 and 913/3444 hospitals). Data comparisons are typically lower than the 1116 and 913 hospitals, as not all survey respondents completed all parts of the survey and the variables used to adjust for severity of illness (health care outcomes) were not available for all hospitals. The mean number of total medication errors reported/year/hospital was 385.83 ± 466.96. The mean number of medication errors reported/year/hospital that adversely affected patient outcomes was 18.99 ± 25.30, or 4.9% (18.99/385.83) of total medication errors/hospital. For each medication error that adversely affected patient care outcomes, 20.32 medication errors were actually reported.

The mean number of admissions/year for the study hospitals was 7611 ± 6514 admissions/hospital or 8,493,876 total admissions (36% of all admissions to U.S. hospitals). The average daily census for study hospitals was 170.3 ± 158.0 patients/day. There were 2.26 ± 3.98 medication errors/occupied bed/year and 0.12 ± 0.25 medication errors that adversely affected patient care outcomes/occupied bed/year. The total number of medication errors was 430,586,

Table 2. Hospital Size and the Number of Medication Errors Reported/Occupied Bed/Year

Size	No. of Hospitals	Medication Errors	Medication Errors that Adversely Affect Patient Care Outcomes
Small	736	2.87 ± 5.36	0.13 ± 0.27
Medium	155	1.55 ± 1.98	0.12 ± 0.28
Large	59	1.34 ± 1.70	0.04 ± 0.26
Significance		F (2, 947) = 6.81, p=0.0012	NS

Table 3. Hospital Teaching Affiliation and the Number of Medication Errors Reported/Occupied Bed/Year

Teaching Affiliation	No. of Hospitals	Medication Errors	Medication Errors that Adversely Affect Patient Care Outcomes
Nonteaching	203	3.43 ± 9.01	0.19 ± 0.33
Nonpharmacy teaching	283	2.62 ± 3.05	0.12 ± 0.27
Pharmacy teaching	534	1.99 ± 2.48	0.07 ± 0.22
Significance		F(2, 1017) = 7.27, p=0.0007	F(2, 772) = 5.04, p=0.025
Teaching hospitals[a]	86	1.62 ± 1.88	0.06 ± 0.13
Nonteaching hospitals	862	2.67 ± 5.04	0.13 ± 0.27
Significance		NS	NS

[a]Members of the Council of Teaching Hospitals or the American Osteopathic Teaching Hospital Association.

whereas 17,338 medication errors were documented that adversely affected patient care outcomes. Medication errors occurred in 5.07% of the patients admitted to these hospitals each year. Each hospital experienced a medication error every 22.7 hours (every 19.73 admissions). Medication errors that adversely affected patient care outcomes occurred in 0.25% of all patients admitted to these hospitals/year. Each hospital experienced a medication error that adversely affected patient care outcomes every 19.23 days (or every 401 admissions).

Table 1 shows the association between census regions and the number of total medication errors and number of medication errors that adversely affected patient care outcomes/occupied bed/year. Medication errors were reported more frequently in the West South Central (3.07 ± 5.09), West North Central (3.25 ± 2.73), and Mountain (3.38 ± 2.56) regions. Medication errors were reported less frequently in the East South Central (2.18 ± 2.18), South Atlantic (2.03 ± 2.39), and Mid-Atlantic (1.32 ± 1.87) regions. Medication errors that adversely affected patient care outcomes were more common in the West North Central (0.14 ± 0.29), West South Central (0.15 ± 0.26), and Mountain (0.24 ± 0.37) regions. Medication errors that adversely affected patient care outcomes were less frequent in the Pacific (0.09 ± 0.26), New England (0.09 ± 0.13), and the Mid-Atlantic (0.05 ± 0.10) regions.

Table 2 shows the associations between hospital size and the number of overall medication errors and the number of medication errors that adversely affected patient care outcomes/occupied bed/year. Medication errors were more common in small (2.87 ± 5.36), than in medium (1.55 ± 1.98) and large (1.34 ± 1.70), hospitals. Table 3 shows the association between pharmacy and hospital teaching affiliation and the number of total medication errors and the number of medication errors adversely affecting patient care outcomes/occupied bed/year. Hospitals that were affiliated with a pharmacy teaching program (1.99 ± 2.48) had a much lower number of total medication errors than hospitals that had nonpharmacy teaching affiliations (2.62 ± 3.05) or no teaching affiliations (3.43 ± 9.01). Likewise, hospitals affiliated with a pharmacy teaching program (0.07 ± 0.22) had a lower number of medication errors that adversely affected patient care outcomes than hospitals that had nonpharmacy teaching affiliations (0.12 ± 0.27) or no teaching affiliations (0.19 ± 0.33).

Table 4 shows the association between type of hospital and the number of total medication errors and the number of medication errors that adversely affected patient care outcomes/occupied bed/year. Federal hospitals had much lower total

Table 4. Hospital Ownership and the Number of Medication Errors Reported/Occupied Bed/Year

Ownership	No. of Hospitals	Medication Errors	Medication Errors that Adversely Affect Patient Care Outcomes
Nonfederal government	71	2.68 ± 3.05	0.15 ± 0.28
Nonprofit	655	2.65 ± 5.57	0.11 ± 0.22
For-profit	145	2.03 ± 2.26	0.16 ± 0.40
Federal government	70	0.89 ± 0.91	0.03 ± 0.07
Significance		F(3, 937) = 3.24, p=0.0214	F(3, 769) = 3.18, p=0.0236

Table 5. Pharmacy Directors' Degrees and the Number of Medication Errors Reported/Occupied Bed/Year

	No. of Hospitals	Medication Errors	Medication Errors That Adversely Affect Patient Care Outcomes
B.S.	513	2.76 ± 3.10	0.13 ± 0.23
Pharm.D.	155	2.53 ± 9.79	0.09 ± 0.14
M.S. Pharmacy	185	1.85 ± 2.69	0.13 ± 0.39
M.B.A., Ph.D., or nonpharmacy master's	164	2.11 ± 3.06	0.12 ± 0.22
Significance		NS	NS

Table 6. Pharmacist Location and the Number of Medication Errors Reported/Occupied Bed/Year

Location	No. of Hospitals	Medication Errors	Medication Errors That Adversely Affect Patient Care Outcomes
Decentralized	474	1.74 ± 2.51	0.09 ± 0.19
Centralized with ward visits	276	1.93 ± 2.14	0.08 ± 0.16
Centralized	265	3.15 ± 6.35	0.15 ± 0.31
Significance		F(2, 1012) = 10.00, p<0.0001	F(2, 826) = 6.31, p=0.0019

medication error rates (0.89 ± 0.91) and medication error rates that adversely affected patient care outcomes (0.02 ± 0.07) than other types of hospitals. Table 5 shows the association between the academic degree of the pharmacy director and the number of total medication errors and the number of medication errors that adversely affected patient care outcomes/occupied bed/year. Hospitals in which the pharmacy director had earned a master of science in pharmacy or a doctor of pharmacy had lower rates of errors than other hospitals (total medication errors, 1.85 ± 2.69; and medication errors that adversely affected patient care outcomes, 0.09 ± 0.14). However, differences between the error rates of these and other hospitals were not statistically significant.

Table 6 shows the association between the physical location of pharmacists within the hospital and the number of total medication errors and the number of medication errors that adversely affected patient care outcomes/occupied bed/year. The lowest numbers of both overall medication errors (1.74 ± 2.51) and medication errors that adversely affected patient care outcomes (0.09 ± 0.19) were seen in hospitals in which pharmacists served in decentralized settings. Hospitals with decentralized pharmacists had a 45% decrease in medication errors (1.81-fold decrease) when compared with hospitals that only had centralized pharmacists. Moreover, hospitals with decentralized pharmacists had a 94% decrease in medication errors that adversely affected patient care outcomes (16.88-fold decrease) when compared with hospitals that had only centralized pharmacists.

Table 7 shows a severity of illness-adjusted multiple regression analysis between medication errors/occupied bed/year and four health care outcome variables: hospital mortality rate, drug costs/occupied bed/year, total cost of care/occupied bed/year, and hospital length of stay. As mortality rate (slope = 3.143, p=0.0043) and total cost of care (slope = 0.027987,

Table 7. Severity of Illness-Adjusted Multiple Regressions between Health Care Outcome Variables and the Number of Medication Errors Reported/Occupied Bed/Year

Health Care Outcome Variables	No. of Hospitals	Slope	SE	Significance	CI	R^2	Adjusted R^2
Mortality rate	987	3.143	1.0341	0.0043	0.9845–5.2083	10.34%	9.21%
Drug costs	966	0.003489	0.002537	NS	-0.001472–0.008443	0.21%	0.10%
Total cost of care	921	0.027987	0.008	0.0062	0.01042–0.04188	11.12%	10.01%
Length of stay	944	0.008441	0.0114	NS	-0.03071–0.01109	0.06%	0.05%

Table 8. Simple Regression between Hospital Staffing/Occupied Bed (919 hospitals) and the Number of Medication Errors Reported/Occupied Bed/Year

Hospital Personnel	Mean No. of Staff/ 100 Occupied Beds	Slope	SE	Significance	95% CI
Administrators	6.98 ± 9.07	2.9931	1.516	0.04	0.1814, 5.968
Physicians	35.41 ± 18.37	-0.8384	0.6359	NS	-2.0852, 0.4092
Ratio of board-certified physicians to all physicians	68.89%	0.036	0.0661	NS	-0.9818, 0.1614
Medical residents	5.12 ± 15.26	-3.1541	1.067	0.0032	-5.2492, -1.0589
Registered nurses	112.67 ± 65.73	0.6908	0.263	0.0008	0.2860, 1.0956
Licensed practical/vocational nurses	29.79 ± 31.03	-0.0045	0.0075	NS	-0.0193, 0.0103
Ratio of registered nurses to licensed practical/vocational nurses	3.19 ± 4.98	2.5563	0.8914	0.0314	0.7619, 4.2971
Physician assistants	0.32 ± 1.34	-0.0755	0.0506	NS	-0.0237, 0.2938
Registered pharmacists	7.21 ± 4.04	9.996	4.2882	0.002	1.5624, 18.4315
Pharmacy technicians	5.81 ± 3.89	-0.0529	0.0177	0.0029	-0.0876, -0.0181
Ratio of registered pharmacists to technicians	1.24 ± 1.36	0.0097	0.1146	NS	-0.2165, 0.2470
Medical technologists	13.57 ± 9.54	3.9998	1.4722	NS	1.1108, 6.8888
Dietitians	1.8 ± 1.95	10.7244	8.2919	NS	-5.5469, 26.9958
Occupational therapists	1.25 ± 3.05	2.5787	7.6464	NS	-12.4258, 17.5834
Physical therapists	3.26 ± 4.28	21.4581	4.6502	0.0001	12.3329, 30.5833
Respiratory therapists	5.98 ± 5.02	4.5336	2.9481	NS	-1.2515, 10.3189
Social workers	2.97 ± 3.06	2.2783	5.1357	NS	-7.8049, 12.3506
Total hospital personnel	506.32 ± 284.23	0.1128	0.0456	0.0082	0.0292, 0.1963

p=0.0062) increased, the number of medication errors also increased. None of these health care outcome variables had statistically significant associations with the number of medication errors that adversely affected patient outcomes.

Table 8 shows a simple regression analysis between medication errors/occupied bed/year and hospital staffing/occupied bed. Several health care staffing ratios are included in this analysis. As the number of hospital administrators (slope = 2.9931, p=0.04), registered nurses (slope = 0.6908, p=0.0008), ratio of registered nurses to licensed practical/vocational nurses (slope = 2.5563, p=0.314), registered pharmacists (slope = 9.996, p=0.002), physical therapists (slope = 21.4581, p=0.001), and total hospital personnel (slope = 0.1128, p=0.0082) increased, the number of medication errors also increased. Conversely, as the number of medical residents (slope = -3.1541, p=0.0032) and pharmacy technicians (-0.0529, p=0.0029) increased, the number of medication errors decreased. These were the only statisti-cally significant associations with this regression model. The only variable that had a statistically significant association with the number of medication errors that adversely affected patient outcomes was the number of medical residents/occupied bed (slope = -0.1571, standard error [SE] = 0.07423, p=0.0346, confidence interval [CI] = -0.3028 to -0.0114).

Table 9 shows a multiple regression analysis between all of the variables presented in tables 1–8 and medication errors/occupied bed/year. Only statistically significant associations are presented. Factors associated with increased total medication errors/occupied bed/year were lack of pharmacy teaching affiliation (slope =

Table 9. Severity of Illness-Adjusted Multiple Regression[a] for All Variables[b] and Medication Errors/Occupied Bed/Year (884 hospitals)

	Slope	SE	Significance	95% CI
Region				
Mid-Atlantic	-1.5182	0.6983	0.03	-2.8887, -0.1475
Teaching affiliation				
No teaching	0.8875	0.3818	0.0416	0.1391, 1.5382
Pharmacy teaching	-1.0252	0.5098	0.0349	-2.0261, -0.0244
Pharmacists' location				
Centralized	1.0942	0.3049	0.0001	0.4951, 1.6932
Decentralized	-0.9843	0.4309	0.0037	-1.782, -0.1494
Hospital staffing				
Medical residents	-1.478	0.5251	0.0014	-2.3601, -0.3448
Registered nurses	1.624	0.758	0.032	0.1361, 3.1119
Pharmacists	25.0573	7.71461	0.0001	11.0199, 39.0948
Outcome measures				
Mortality rate	2.8017	0.8915	0.0192	1.2902, 3.8921
Total cost of care	0.01432	0.005619	0.0091	0.003218, 0.02692

[a]R^2 = 21.03%; adjusted R^2 = 15.94%
[b]All variables from Tables 1–8. Only statistically significant associations are reported.

0.8875, p=0.0416), centralized pharmacists (slope = 1.0942, p=0.0001), number of registered nurses/occupied bed (slope = 1.624, p=0.032), number of registered pharmacists/occupied bed (slope = 25.0573, p=0.0001), hospital mortality rate (slope = 2.8017, p=0.0192), and total cost of care/occupied bed/year (slope = 0.01432, p=0.0091). Factors associated with decreased medication errors were location in the Mid-Atlantic region (slope = -1.5182, p=0.03), affiliation with a pharmacy teaching program (slope = -1.0252, p=0.0349), decentralized pharmacists (slope = -0.9843, p=0.0037), and number of medical residents/occupied bed (slope = -1.478, p=0.0014). The actual R^2 for this analysis was 21.03%, and the adjusted R^2 was 15.94%. A similar multiple regression analysis was performed with medication errors that adversely affected patient outcomes. This analysis was not statistically significant.

Discussion

In the 1116 hospitals studied, 5.07% of patients experienced a medication error. This figure is consistent with the medication error rates of 3–6.9% reported in smaller studies.[2, 7–10] We found that 0.25% of patients experienced a medication error that adversely affected their care; this figure is somewhat lower than the rate of comparable errors identified in previous reports (0.7%).[2] In addition, the finding that 4.9% of all medication errors adversely affected patient care outcomes (18.99 ± 25.30 medication errors that adversely affected patient care outcomes/hospital ÷ 385.83 ± 466.96 medication errors/hospital) is somewhat higher than the comparable figure (3%) reported by the U.S. Pharmacopeia.[14] Since all previous studies of medication errors involved few hospitals or a limited number of patients, our results are probably a more accurate reflection of the actual health care system. Our study, which examined 430,586 medication errors, was 69 times larger than the analysis conducted by the U.S. Pharmacopeia, which relied on data voluntarily provided to that institution for 1999 (6224 medication errors).[14] Whereas we can not assess how many medication errors go unreported, it is likely that a substantial number of medication errors were not detected or reported to the hospital medication error reporting system.

The exact reasons for the differences in total medication errors and medication errors that adversely affected patient care outcomes based on census regions are unknown. Pharmacy services and drug costs have been shown to vary significantly by geographic region.[16, 30, 32, 34, 45, 46] The Mid-Atlantic region generally has lower levels of clinical pharmacy services when compared with other regions.[16] In addition, fewer hospitals in the Mid-Atlantic region have decentralized pharmacists.[16] The Mid-Atlantic region, which had a low number of medication errors, had the lowest drug costs/occupied bed/year in 1992.[30] The West South Central, Mountain, and Pacific regions, which had higher numbers of medication errors, tended to have higher drug costs/occupied bed/year. Since drug costs probably represent an indirect measure of the number of drugs dispensed/patient, these findings simply may be related to number of drugs used/patient rather than any specific hospital or regional factors. This finding also could be explained by pharmacist workload, in that more drugs/patient (in regions with higher drug costs) may indicate a higher workload for the pharmacy (medication orders/hour). It previously was shown that the risk of medication errors increases substantially when the number of medication orders/hour increases.[47-50] Whereas the risk of medication errors increases as pharmacist workload increases, there appears to be a critical point (20–25 prescription orders/hour) at which errors dramatically increase.[47-50]

The exact reasons for the differences between smaller and larger hospitals with regard to total medication errors and medication errors that adversely affected patient care outcomes are unknown. Smaller hospitals reported almost twice the frequency of medication errors compared with medium and large hospitals. In our previous publications, we reported that smaller hospitals provided fewer clinical pharmacy services and had fewer clinical pharmacists when compared with medium and large hospitals.[16, 31, 33, 34] This finding may suggest that smaller hospitals lack the level of patient care services and/or training necessary to reduce medication errors. Clearly, further study is needed to determine the specific reasons why medication errors are affected by hospital size.

One of the more striking findings of this study is the association between pharmacy teaching affiliation and medication errors, including medication errors that adversely affect patient care outcomes. Hospitals that had no teaching affiliations reported a medication error rate 72% greater than hospitals affiliated with pharmacy teaching programs (3.43 ± 9.01 vs 1.99 ± 2.48). Likewise, hospitals that had no teaching affiliation reported 171% more medication errors that adversely affected patient care outcomes than hospitals affiliated with pharmacy teaching programs (0.19 ± 0.33 vs 0.07 ± 0.22). The exact reasons for these findings are unknown.

We previously reported that hospitals affiliated with pharmacy teaching programs had significantly more clinical pharmacy services and employed more clinical pharmacists than hospitals without such affiliations.[16, 31, 32, 34] Whether the increased provision of clinical pharmacy services to patients in these hospitals is related to lower medication errors is unknown. Perhaps pharmacy teaching hospitals have patient care services and/or training that helps reduce medication errors. Student training and supervision may lead to greater scrutiny of medication orders and the dispensing process. In addition, it is also likely that colleges of pharmacy affiliate with better hospitals that provide more clinical services than other hospitals. It appears that pharmacy teaching affiliation is a more important factor in the reduction of medication errors than hospital teaching affiliation (i.e., membership in the Council of Teaching Hospitals or the American Osteopathic Teaching Hospital Association).

The reasons for lower rates of total medication errors and medication errors that adversely affect patient care outcomes in federal government hospitals are unknown. When compared with the mean medication error rate for all study hospitals, federal government hospitals had a 65% lower rate of medication errors (0.89 ± 0.91 vs 2.53 ± 3.98) and a 77% lower rate of medication errors that adversely affect patient care outcomes (0.3 ± 0.07 vs 0.13 ± 0.25). This may be due to fewer drugs being used in federal government hospitals, since drug costs/occupied bed/year in federal government hospitals were 24% lower when compared with all hospitals in the study population ($2291 ± $1279 vs $2997 ± $1267).[30] It is also worth noting that federal government hospitals generally had higher levels of clinical pharmacy services compared with other types of hospitals.[16]

Whereas the associations between a pharmacy director's academic degree and total medication errors and medication errors adversely affecting patient care outcomes were not statistically significant, the trend of this analysis suggests that directors with advanced degrees were in hospitals that had fewer medication errors. It is interesting to note that directors with advanced degrees generally served in hospitals offering higher levels of clinical pharmacy services when compared with directors who had only a bachelor's degree.[16, 31, 32, 34]

Although the fundamental reasons for lower rates of total medication errors and medication errors that adversely affected patient care outcomes in hospitals with decentralized pharmacists are unknown, this finding is not surprising. Previous studies documented that a clinical pharmacist providing decentralized services on work rounds in an ICU decreases preventable adverse drug events by 66%.[51] In addition, in a study of two teaching hospitals, ward-based clinical pharmacists reduced potential adverse drug events (medication errors judged to have significant potential for injuring a patient) by 94%.[52] This variable accounted for some of the most dramatic differences in medication error rates. We found a 45% (1.81-fold) decrease in total medication errors in hospitals that had decentralized pharmacists when compared with hospitals that exclusively had centralized pharmacists. In addition, there was a 94% (16.88-fold) decrease in medication errors that adversely affected patient care outcomes in hospitals with decentralized pharmacists when compared with hospitals that had only centralized pharmacists. This finding is identical to the results of a field study of adverse drug events in children in two Boston hospitals.[52] It appears that one of the most effective ways to prevent medication errors that actually harm patients is to decentralize pharmacists to patient care areas.

Hospitals with decentralized pharmacists had more clinical pharmacists and much higher levels of clinical pharmacy services than hospitals in which all pharmacists were centralized.[16, 31, 32, 34] Substantial documentation indicates that clinical pharmacy services can improve therapeutic outcomes and reduce drug costs.[17–21, 53–65] Providing clinical pharmacy services in a decentralized location may reduce medication errors by reducing inappropriate prescribing and improving the monitoring of patients. Decentralized pharmacists often serve as a final check on drugs provided from the central pharmacy. Previous field studies involving decentralized clinical pharmacists in three hospitals,[51, 52] in addition to our findings in 1116 hospitals, strongly suggest that decentralizing pharmacists may be one of the most effective ways to decrease medication errors. Additional study will be needed to elucidate the specific services of decentralized pharmacists that reduce medication error rates.

We found that as total medication errors and medication errors that adversely affect patient care outcomes increased, hospital mortality rates, drug costs/occupied bed, total cost of care/occupied bed, and length of stay also increased. However, only two of these measures were statistically significant: mortality rate (slope = 3.143, $p=0.0043$, $R^2 = 10.34\%$) and total cost of care (slope = 0.027987, $p=0.008$, $R^2 = 11.12\%$). These associations seem logical, since medication errors can lead to increased deaths, morbidity, and hospital costs.[1–10] Since mortality rates are very good indicators of the quality of patient care,[25, 26, 38–40] lower medication error rates are likely to indicate better quality of care. This is the first study to show that increased medication errors predict increased mortality rates and increased total cost of care in a large number of hospitals. This finding demonstrates that medication errors are not isolated events that only affect individual patients; they have a negative impact on health care and system financials.

The multiple regression analysis is the most important of our statistical analyses. Factors associated with increased medication errors/occupied bed/year were lack of pharmacy teaching affiliation (slope = 0.8875, $p=0.0416$), centralized pharmacists (slope = 1.0942, $p=0.0001$), the number of registered nurses/occupied bed (slope = 1.624, $p=0.032$), the number of registered pharmacists/occupied bed (slope = 25.0573, $p=0.0001$), hospital mortality rate (slope = 2.8017, $p=0.0192$), and total cost of care/occupied bed/year (slope = 0.01432, $p=0.0091$). Factors associated with decreased medication errors were location in the Mid-Atlantic region (slope = -1.5182, $p=0.03$), affiliation with a pharmacy teaching program (slope = -1.0252, $p=0.0349$), decentralized pharmacists (slope = -0.9843, $p=0.0037$), and the number of medical residents/occupied bed (slope = -1.478, $p=0.0014$). Whether the lower mortality rates observed in hospitals with larger numbers of medical residents were due to better care, the involvement of more physicians in the care of patients, or simply to decreased resident caseload is unknown. Although we did not specifically measure medical resident workload (number patients/resident), our data suggest that this variable was probably associated with the rate of medication errors. The data show that hospitals with larger medical teaching programs were associated with lower medication error rates. This finding is consistent with studies of pharmacist workloads, which demonstrate that increased workloads are associated with increased rates of medication errors.[47–50]

As the number of registered nurses and pharmacists/occupied bed increased, more medication errors were detected. In the simple regression analysis, as the number of licensed practical/vocational nurses and pharmacy technicians increased, fewer medication errors were detected. A study published in 1997 found that 11.4% of 2103 medication errors were due to the wrong drug or dosage (dispensing errors).[8] Similarly, a 1995 study found that 11% of medication errors were pharmacy dispensing errors related to the wrong drug or incorrect strength.[9] Most of the medication errors addressed in the 1997 study involved factors such as insufficient knowledge of drug therapy (30%), lack of awareness of patient's condition (e.g., kidney function) (29.3%), and inaccurate calculations and unit or rate expression factors (17.5%). Other investigators have shown similar results.[1-3] It appears that only a small minority of medication errors are due to the wrong drug or dosage. Higher cognitive skills are required to detect and report the vast majority of medication errors. Our findings with registered nurses, registered pharmacists, licensed practical/vocational nurses, and pharmacy technicians suggest that better educated and trained personnel (registered nurses and registered pharmacists) may be necessary to detect medication errors caused by lack of drug and patient care information. This conclusion is also supported by previous studies showing that pharmacists and technicians are about equally accurate when simply checking drugs for correct drug and dosage form.[66-70] However, pharmacists performed much better than licensed vocational nurses in detecting medication errors when these errors involved interpreting patient care data.[71] Unfortunately, there are no studies evaluating the abilities of pharmacists and pharmacy technicians to detect this type of medication errors.

The findings regarding hospital staffing suggest that physicians (medical residents) may be more involved with producing medication errors (workload-prescribing), whereas registered nurses and registered pharmacists may be more involved in detecting and reporting medication errors. The data on licensed practical/vocational nurses and pharmacy technicians suggest that the presence of highly trained nurses and pharmacists in patient care areas is essential to detection and reporting of medication errors. It also appears the location of pharmacists is very important for the reduction of medication errors. For pharmacists, it appears that increased staffing is desirable and that staff should be decentralized to improve the quality of patient care.

Clearly, the results of this study provide some direction for reducing medication errors in U.S. hospitals. Census region, hospital size, pharmacy teaching affiliation, type of hospital, location of pharmacists, mortality rates, total cost of care, as well as staffing for medical residents, registered nurses, and registered pharmacists, play important roles in medication error rates.

Limitations

Data from this study are from 1992 and may not be representative of health care in 2001. It is possible that the information provided to us was inaccurate. We did not attempt to verify information by phone contact or through hospital visitation. Since this is the first large-scale study of factors associated with medication errors in hospitals, these findings will need to be replicated in future studies. This study design allowed us to determine association and direct relationships between variables, but it did not allow us to determine causality. Therefore, these findings should not be construed as cause and effect. It is possible that the hospitals in our study population were not representative of all U.S. hospitals. However, this is doubtful, since the study population represented 32% of all U.S. hospitals.[35, 36] Given that this was a population-based survey study, we could not determine the specific types of medication errors. Nor could we gather specific information about each medication error and the types of harm experienced by patients. Unfortunately, there is no national standard that hospitals use to categorize medication errors. Since medication errors were likely underreported, actual error rates were likely higher than reported. Caution should be employed in applying these findings to individual pharmacies or hospitals.

Conclusion

This is the first large-scale study to determine relationships between hospital demographics, staffing, pharmacy variables, health care outcomes (severity of illness-adjusted mortality rates, drug costs, total cost of care, and length of stay) and medication errors. The multiple regression analysis found the following factors to be associated with increased medication errors/occupied bed/year: lack of pharmacy teaching affiliation, centralized pharmacists, number of registered nurses/occupied bed, number of registered pharmacists/occupied bed, hospital mortality rate, and total cost of care/occupied bed/year. Factors associated with decreased medication errors were location in the Mid-Atlantic census region, affiliation with a pharmacy teaching program, decentralized pharmacists, and the number of medical residents/occupied bed. It our sincere hope that pharmacy directors, clinicians, hospital administrators, and health care policy consultants will use the results of this study to reduce the risks for medication errors. Clearly, hospital staffing models should consider decentralized pharmacists and linkage to teaching programs.

Acknowledgment

We would like to gratefully acknowledge Roland Patry, D.P.H., R.Ph., for his assistance in preparing this manuscript.

References

1. Institute of Medicine. To err is human: building a safer health care system. Washington, D.C.: National Academy Press, 1999.
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. N Engl J Med 1991;324:370–6.
3. Leape LL, Brennan TA, Laird NM, et al. The nature of adverse events in hospitalized patients. N Engl J Med 1991;324:377–84.
4. National Center for Health Statistics, Centers for Disease Control and Prevention. Deaths: final data for 1997. Natl Vital Statistics Rep 1999;47(25):6.
5. Thomas EJ, Studdert DM, Newhouse JP, et al. Costs of medical injuries in Utah and Colorado. Inquiry 1999:36:255–64.
6. Johnson WG, Brennan TA, Newhouse JP, et al. The economic consequences of medical injuries. JAMA 1992;267:2487–92.
7. Dean BD, Allan EL, Barber ND, et al. Comparison of medication errors in an American and British hospital. Am J Hosp Pharm 1995:52:2543–9.
8. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. JAMA 1997:277(4):312–17.
9. Bates DW, Boyle DL, Vander VM, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. JAMA 1995;274:29–34.
10. Nelson KM, Talbert RL. Drug-related hospital admissions. Pharmacotherapy 1996:16(4):701–7.
11. Folli HL, Poole RL, Benitz WE, et al. Medication error prevention by clinical pharmacists in two children's hospitals. Pediatrics 1987;79:718–22.
12. Borel JM, Rascati KL. Effects of an automated, nursing unit-based drug-dispensing device on medication errors. Am J Health-Syst Pharm 1995;52:1875–9.
13. Barker KN, Pearson RE, Hepler CD, et al. Effects of an automated bedside dispensing machine on medication errors. Am J Hosp Pharm 1984;41:1352–8.
14. United States Pharmacopeia. Summary of the 1999 information submitted to MedMAR$_X$, a national database for hospital medication error reporting. Available from www.usp.org/medmarx.
15. Work DR, Madigan MA. Initiatives for medication error reduction. US Pharmacist 1997;22:1–12.
16. Bond CA, Raehl CL, Pitterle ME. 1992 National clinical pharmacy services study. Pharmacotherapy 1994;14(3): 282–304.
17. Pitterle ME, Bond CA, Raehl CL, Franke T. Hospital and pharmacy characteristics associated with mortality rates in United States hospitals. Pharmacotherapy 1994;14(5):620–30.
18. Bond CA, Raehl CL, Pitterle ME, Franke T. Health Care professional staffing, hospital characteristics, and hospital mortality rates. Pharmacotherapy 1999;19(2):130–8.
19. Bond CA, Raehl CL, Franke T. Clinical pharmacy services and hospital mortality rates. Pharmacotherapy 1999;19(5):767–81.
20. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacist staffing, and drug costs in United States hospitals. Pharmacotherapy 1999;19(12):1354–62.
21. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacy staffing, and the total cost of care in United States hospitals. Pharmacotherapy 2000:20(6):609–21.
22. Bond CA, Raehl CL, Franke T. Interrelationships among mortality rates, drug costs, total cost of care, and length of stay in United States hospitals: summary and recommendations for clinical pharmacy services and staffing. Pharmacotherapy 2001;21(2):129–41.
23. Kuhn EM, Hartz AJ, Gottlieb MS, Rimm AA. The relationship of hospital characteristics and results of peer review in six large hospitals. Med Care 1991;29:1028–38.
24. Green J, Passman LJ, Wintfield N. Analyzing hospital mortality: the consequences of diversity in patient mix. JAMA 1991;265:1849–53.
25. Hartz AJ, Gottlieb M, Kuhn EM, Rimm A. A national validation study of Medicare mortality studies (project #1247-M). Technical report to the Health Standards Review Bureau. Washington, DC: U.S. Government Printing Office, 1989.
26. Hartz AJ, Krakauer H, Kuhn EM, et al. Hospital characteristics and mortality rates. N Engl J Med 1989;321:1720-5.
27. Kelly JV, Hellinger FJ. Physician and hospital factors associated with mortality in surgical patients. Med Care 1986;24:785-800.
28. Shortell SM, Hughes EFX. The effect of regulation, competition, and ownership on mortality rates among hospital inpatients. N Engl J Med 1988;318:1100-7.
29. Daley J, Jencks S, Draper D, et al. Predicting hospital-associated mortality for Medicare patients. JAMA 1988:260:3614–17.
30. Bond CA, Raehl CL, Pitterle ME. Cost of pharmaceutical services in U.S. hospitals in 1992. Am J Hosp Pharm 1995;52:503–613.
31. Raehl CL, Bond CA. 1998 National clinical pharmacy services study. Pharmacotherapy 2000;20(4):436–60.
32. Raehl CL, Bond CA, Pitterle ME. 1995 National clinical pharmacy services survey. Pharmacotherapy 1998;18(2): 282–304.
33. Raehl CL, Bond CA, Pitterle ME. Hospital pharmacy services in the Great Lakes region. Am J Hosp Pharm 1990;47: 1283–303.
34. Raehl CL, Bond CA, Pitterle ME. Pharmaceutical services in U.S. hospitals in 1989. Am J Hosp Pharm 1992;49:323–46.
35. Health Care Financing Administration. Medicare hospital mortality information (on data tape). Washington, DC: Healthcare Financing Association, 1992.
36. American Hospital Association. American Hospital Association abridged guide to the health care field (on diskettes). Chicago, IL: American Hospital Association, 1992.
37. Stata Corporation. Stata statistical software release 7.0 product information. College Station, TX: 2001.
38. Dubois RW, Brooks RH, Rodgers WH. Adjusted hospital death rates: a potential screen for quality of medical care. Am J Public Health 1987:77:1162–7.
39. Keeler EB, Rubenstein LV, Kahn KL, et al. Hospital characteristics and quality of care. JAMA 1992;268:1709–14.
40. Krakauer H, Bailey RC, Skellan KJ, Stewart JD, Hartz AJ. Evaluation of the HCFA model for the analysis of mortality following hospitalization. Health Services Res 1992;27(3): 317–35.
41. Green J, Wintfield N, Sharkey P, Passman LJ. The importance of severity of illness measures in assessing hospital mortality. JAMA 1990;262:241–6.
42. Wampole BE, Freund RD. Use of multiple regression in counseling psychology research: a flexible data analytic strategy. J Counsel Psychol 1987;34:372–82.
43. Pedhazur EJ. Multiple regression in behavioral research: explanation and prediction, 2nd ed. New York: Harcourt Brace Jovanovich, 1982.
44. Babbie E. The practice of social research, 8th ed. Boston: Wadsworth Publishing Company. 1998.
45. Bond CA, Raehl CL, Pitterle ME. Staffing and the cost of

clinical and hospital pharmacy services in United States hospitals. Pharmacotherapy 1999;19(6):767–81.
46. Pitterle ME, Bond CA, Raehl CL. A comprehensive measure of pharmaceutical services: the pharmaceutical care index. Am J Hosp Pharm 1990;47:1304–13.
47. Bond CA, Raehl CL. Pharmacists' assessment of dispensing errors: risk factors, practice sites, professional functions, and satisfaction. Pharmacotherapy 2001:21(5):614–26.
48. Kistner UA, Keith MR, Sergeant KA, et al. Accuracy of dispensing in a high-volume, hospital-based outpatient pharmacy. Am J Hosp Pharm 1994;51:2793–7.
49. Allan EL, Barker KN, Malloy M, et al. Dispensing errors and counseling in community practice. Am Pharm 1995; NS35:25–33.
50. Allan EL. Relationships among facility design variables and medication errors in pharmacy [dissertation]. Microfilm 9430107. Auburn, AL: Auburn University. 1994.
51. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacists' participation on physician rounds and adverse drug events in the intensive care unit. JAMA 1999:282:267–70.
52. Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. JAMA 2001;285:2114–20.
53. Black BL. Resource book on progressive pharmaceutical services. Bethesda. MD: American Society of Hospital Pharmacists. 1986.
54. Hatoum HT, Catizone C, Hutchinson RA, et al. An eleven-year review of the pharmacy literature: documentation of the value and acceptance of clinical pharmacy. Drug Intell Clin Pharm 1986;20:33–48.
55. Comptroller General of the United States. Study of health facilities construction costs. Washington, DC: U.S. Government Printing Office 1972:68–72,363–79.
56. Barker KN, Pearson RE. Medication distribution systems. In: Brown TR, Smith MC, eds. Handbook of institutional pharmacy practice. Baltimore: Williams & Wilkins, 1986:325–51.
57. Elenbaas RM, Payne VW, Bauman JL. Influence of clinical pharmacists' consultations on the use of blood level test. Am J Hosp Pharm 1980;37:61–4.
59. Bollish SJ, Kelly WN, Miller DE, et al. Establishing an aminoglycoside pharmacokinetic monitoring service in a community hospital. Am J Hosp Pharm 1981;38:73–6.
59. Abramowitz PA, Nold EC, Hatfield SM. Use of clinical pharmacists to reduce cefamandole, cefoxitin, and ticarcillin costs. Am J Hosp Pharm 1982;39:1176–80.
60. Herfindal ET, Bernstein LR, Kishi DT. Effect of clinical pharmacy services on prescribing on an orthopedic unit. Am J Hosp Pharm 1983:40:1945–51.
61. Knapp DE, Knapp DA, Speedie MK, et al. Relationship of inappropriate drug prescribing to increased length of hospital stay. Am J Hosp Pharm 1979;36:1334–7.
62. Knapp DE, Speedie MK, Yaeger DM, et al. Drug prescribing and its relationship to length of hospital stay. Inquiry 1980;17:254-9.
63. McKenney JM, Wasserman, AH. Effect of advanced pharmaceutical services on the incidence of adverse drug reactions. Am J Hosp Pharm 1979;36:1691–7.
64. Clapham CE, Hepler CE, Reinders TP, et al. Economic consequences of two drug-use control systems in a teaching hospital. Am J Hosp Pharm 1988;45:2329–40.
65. Bjornson DC, Hiner WO, Potyk RP, et al. Effect of pharmacist on health care outcomes in hospitalized patients. Am J Hosp Pharm 1993;50:1875–84.
66. Grogran JE, Hanna JA, Haight RA. A study of accuracy of pharmacy technicians working in a unit dose system. Hosp Pharm 1978;13:194–201.
67. Becker MD, Johnson MH, Longe RL. Errors remaining in unit dose carts after checking by pharmacists versus pharmacy technicians. Am J Hosp Pharm 1978:35;432–6.
68. Woller TW, Stuart J, Vrabel R, Senst B. Checking of unit dose cassettes by pharmacy technicians at three Minnesota hospitals. Am J Hosp Pharm 1991:48:1952–8.
69. Klammer GA, Ensom R. Pharmacy technician refill checking: safe and practical. Can J Hosp Pharm 1994:47:117–23.
70. Ness JE, Sullivan SD, Stergachis A. Accuracy of technicians and pharmacists in identifying dispensing errors. Am J Hosp Pharm 1994:51:354–9.
71. Facchinetti NJ, Campbell GM, Jones DP. Evaluating dispensing error detection rates in a hospital pharmacy. Med Care 1999:37:39–43.

Appendix. Definitions and Groupings Used in Analysis

Geographic regions
- New England: Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont
- Mid-Atlantic: New Jersey, New York, Pennsylvania
- South Atlantic: Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
- East North Central: Illinois, Indiana, Michigan, Ohio, Wisconsin
- East South Central: Alabama, Kentucky, Mississippi, Tennessee
- West North Central: Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
- West South Central: Arkansas, Louisiana, Oklahoma, Texas
- Mountain: Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
- Pacific: Alaska, California, Hawaii, Oregon, Washington

Hospital size
- Small: average daily census (ADC) < 200
- Medium: ADC 200–399
- Large: ADC ≥ 400

Hospital teaching affiliation
- Nonteaching hospital: not associated with a college of pharmacy, school of medicine, school of nursing, allied health care program, master of science (M.S.) or master of business administration (M.B.A.) degree program.
- Nonpharmacy teaching hospital: affiliated with a school of medicine, school of nursing, allied health care program, M.S. or M.B.A. program but not with a college of pharmacy.
- Pharmacy teaching hospital: affiliated with a college of pharmacy degree program [bachelor of science (B.S.), M.S., doctor of pharmacy (Pharm D.)].

Appendix. Definitions and Groupings Used in Analysis (continued)

Pharmacist's location
- Decentralized: dispensing functions supported mostly by a central pharmacy, satellite pharmacies, or mobile carts.
- Centralized: pharmacists occasionally may visit patient care units but not on a daily basis.
- Centralized with ward visit: pharmacists visit patient care units at least once/day.Pharmacy director's education
- B.S.: pharmacy degree only.
- M.B.A., Ph.D., nonpharmacy master's: directors with one of these degrees also may have completed a B.S. in pharmacy.
- M.S. in pharmacy: directors also may have completed a B.S. in pharmacy or Pharm D.
- Pharm D.: directors also may have a B.S.

Hospital ownership
- Government, nonfederal: state, country, city-county, or hospital district or authority
- Nongovernment nonprofit: church-operated or other
- Investor-owned (for-profit): individual, partnership, or corporation
- Government, federal: Air Force, Army, Navy, Public Health Service, Veterans Administration, Public Health Service, Indian Service, Department of Justice

Attachment 4 (4)

Susan Ravnan

From: shane@cshs.org
Sent: Monday, January 16, 2006 5:33 PM
To: Susan Ravnan; cfountz@cshp.org; shane@cshs.org
Subject: pharmacist on rounds

Ovid Technologies, Inc. Email Service

Results: JAMA: The Journal of the American Medical Association

Volume 282(3), 21 July 1999, pp 267-270

Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit
[Caring For The Critically Ill Patient]

Leape, Lucian L. MD; Cullen, David J. MD; Clapp, Margaret Dempsey MS, RPh; Burdick, Elisabeth MS; Demonaco, Harold J. MS, RPh; Erickson, Jeanette Ives MSN, RN; Bates, David W. MD, MSc
Author Affiliations: Department of Health Policy and Management, Harvard School of Public Health (Dr Leape and Ms Burdick); Departments of Anesthesia (Dr Cullen), Pharmacy (Ms Clapp and Mr Demonaco), and Nursing (Ms Erickson), Massachusetts General Hospital; and Division of General Internal Medicine, Brigham and Women's Hospital (Dr Bates), Boston, Mass.

Outline

Abstract

Context: Pharmacist review of medication orders in the intensive care unit (ICU) has been shown to prevent errors, and pharmacist consultation has reduced drug costs. However, whether pharmacist participation in the ICU at the time of drug prescribing reduces adverse events has not been studied.

Objective: To measure the effect of pharmacist participation on medical rounds in the ICU on the rate of preventable adverse drug events (ADEs) caused by ordering errors.

Design: Before-after comparison between phase 1 (baseline) and phase 2 (after intervention implemented) and phase 2 comparison with a control unit that did not receive the intervention.

Setting: A medical ICU (study unit) and a coronary care unit (control unit) in a large urban teaching hospital.

Patients: Seventy-five patients randomly selected from each of 3 groups: all admissions to the study unit from February 1, 1993, through July 31, 1993 (baseline) and all admissions to the study unit (postintervention) and control unit from October 1, 1994, through July 7, 1995. In addition, 50 patients were selected at random from the control unit during the baseline period.

: A senior pharmacist made rounds with the ICU team and remained in the ICU for consultation in the morning, and was available on call throughout the day.

Main Outcome Measures: Preventable ADEs due to ordering (prescribing) errors and the number, type, and acceptance of interventions made by the pharmacist. Preventable ADEs were identified by review of medical records of the randomly selected patients during both preintervention and postintervention phases. Pharmacists recorded all recommendations, which were then analyzed by type and acceptance.

· The rate of preventable ordering ADEs decreased by 66% from 10.4 per 1000 patient-days (95% confidence interval [CI], 7-14) before the intervention to 3.5 (95% CI, 1-5; P

Conclusions: The presence of a pharmacist on rounds as a full member of the patient care team in a medical ICU was associated with a substantially lower rate of ADEs caused by prescribing errors. Nearly all the changes were readily accepted by physicians.

JAMA.1999;282:267-270

In traditional hospital practice most of the burden of drug therapy decision making falls on the physician. However, studies have shown that physicians sometimes make errors in prescribing drugs. [1,2] While most errors are harmless or are intercepted, some result in adverse drug events (ADEs). The pharmacist's role in prescribing is typically reactive: responding to prescription errors long after the decision has been made for patients about whom he or she has little direct clinical knowledge. Thus, the specialized knowledge of the pharmacist is not utilized when it would be most useful: at the time of ordering.

Studies show that pharmacist retrospective review of medication orders prevents errors. [3-5] However, the pharmacist's impact might be substantially greater if he or she could provide input earlier, at the time of prescribing. It has been shown that pharmacist consultation with physicians and others in an intensive care unit (ICU) resulted in a net saving from reduced drug use of $10,011 in a 3-month period. [6] However, we know of no controlled studies that have evaluated the effect of pharmacist participation on the key outcome measure of error prevention-the rate of ADEs.

For these reasons, we conducted a controlled clinical trial of the efficacy of pharmacist participation in physician rounds in a medical ICU as part of a continuing study of systems changes to prevent ADEs. The ADE rate is higher among patients in ICUs, both because they have pathophysiological abnormalities and often receive many drugs.

We asked the following questions: (1) Is pharmacist participation on rounds associated with a reduction in the rate of preventable ADEs? (2) What types of interventions does the pharmacist make? and (3) Is pharmacist participation on ICU rounds accepted by physicians and nurses?

METHODS

The study was carried out in 2 medical ICUs at Massachusetts General Hospital, a large tertiary care hospital in Boston, during 2 periods: February 1, 1993, through July 31, 1993 (phase 1, preintervention), and October 1, 1994, through July 7, 1995 (phase 2, postintervention).

The study unit was a 17-bed medical ICU and the control unit was a 15-bed coronary care unit (CCU). The average daily census was 13.9 in the medical ICU and 12.9 in the CCU during phase 1 and 12.4 and 11.9, respectively, during phase 2. Nurse and physician staffing ratios were similar in the 2 units. Patients in the medical ICU had a range of acute and chronic medical illness other than primary cardiac disease, while those in the CCU were primarily cardiac patients. Each unit frequently admitted both categories of patients when the other unit was full. Patients receiving ventilatory support constituted 70% of patients in the medical ICU and 60% of patients in the CCU.

Sample

We compared outcomes in the study unit before and after the intervention, and between the study unit and a control unit during the same period after the intervention. Using a random number generator, we selected 75 patients from each of 3 groups: all patients admitted to the study unit during phase 1 and phase 2 and all patients admitted to the control unit during phase 2. To detect whether unmeasured variables may have altered the rate of ADEs (secular trend), we also randomly selected 50 patients from all those admitted to the control unit during phase 1.

The intervention was the assignment of an experienced senior pharmacist to make rounds with the patient care team in the study ICU. The pharmacist made rounds with the residents, nurses, and attending staff each morning, was present in the unit for consultation and assistance to the nursing staff during the rest of the morning, and was available on call as necessary throughout the day. The total commitment was approximately half of the pharmacist's time. In the control ICU, as is the usual practice, another pharmacist was available in the unit for part of the day but did not make rounds with physicians and nurses. The intervention began in May 1994. Data collection began in October 1994 and continued through July 1995.

Outcome Measures

We assessed the effect of pharmacist participation with 2 measures: (1) the change in the rate of preventable ADEs in the ordering stage and (2) the number and acceptance of interventions recommended by the pharmacist. We defined an ADE as an injury related to the use of a medication. A preventable ADE is an injury caused by an error in the use of a medication (eg, hypotension or hypoglycemia, changes in mental status, bleeding, or cardiac arrest). [1]

Adverse Drug Events

Using previously described methods, [7] trained and experienced investigators (1 nurse and 1 pharmacist) identified incidents (apparent medication errors or ADEs) by review of medical records in which they examined all progress notes, orders, and laboratory results during the index admission.

Incidents were evaluated independently by 2 physician reviewers (L.L.L. and D.W.B.) who classified them according to whether or not an ADE or potential ADE was present. Using pre-established criteria, [7] they also made judgments of severity, preventability, and, if an error was present, the type of error and the stage in the process at which the error occurred. When there were disagreements the reviewers met and reached consensus. If consensus could not be reached, a third reviewer evaluated the incident. Reliability for these judgments has previously been reported [7](for judgments about whether an incident was an ADE, kappa=0.81-0.98; for preventability, kappa=0.92; and for severity, kappa=0.32-0.37). All reviewers and investigators were blinded to patient group assignment.

Pharmacist Interventions

To develop descriptive information about changes suggested by the pharmacist, we measured the number of interventions, the type of intervention, and the percentage of recommendations accepted. For this purpose, the pharmacist completed a report form for each intervention that could potentially lead to a change in orders, noting the date, drug, nature of the order, the specific recommendation, and whether or not it was accepted by the physicians. The type of intervention was then classified as shown in (Table 1). The pharmacist also recorded events that did not involve order changes, such as errors in the pharmacy system or identification of ADEs.

Table 1. Pharmacist Interventions

Analysis

The primary measure used to assess the effect of the interventions was the rate of preventable ADEs due to prescribing errors. We conducted comparisons at 2 points in time in the study unit, before and after the intervention, and between the study and control units after the intervention.

For the before-after evaluation, we compared the rate of occurrence of preventable ordering ADEs among patients in the study unit during phase 1 with the rate in the same unit during phase 2. For the between-unit comparison, we compared the rate in the study unit during phase 2 with the rate of occurrence in the control unit in phase 2. To assess potential secular trends, we also compared the rate in the control unit in phase 1 with its rate in phase 2.

Comparisons between rates in phases 1 and 2 in the study unit (before and after) and between the study unit and the control unit in phase 2 (contemporaneous) were made using unpaired t tests. Analyses were performed using SAS statistical software. [8]

RESULTS

ADE Rates

The overall rates, expressed as preventable ordering ADEs per 1000 patient-days, are shown for both phases for both units in (Table 2). In the before and after comparison, the rate of preventable ordering ADEs per 1000 patient-days decreased in the study unit by 66% from phase 1 to phase 2 (10.4 [95% CI, 7-14] to 3.5 [95% CI, 1-5]; P

Table 2. Adverse Drug Event Rates*

When the intervention unit was compared with the control unit during the same time period (phase 2), the rate of preventable ordering ADEs in the study unit was 72% lower than in the control unit (3.5 [95% CI, 1-5] vs 12.4 [95% CI, 8-17] per 1000 patient-days; P

When results were calculated in terms of number of patients (admissions), the differences in rates were similar: in the study unit, the rate of preventable ordering ADEs decreased by two thirds, from 12% in phase 1 to 4% in phase 2, while it was essentially unchanged in the control unit (10% to 11%).

The rate of all ADEs also decreased substantially in the study unit from phase 1 to phase 2 (33.0 [95% CI, 27-39] to 11.6 [95% CI, 8-15]; P

Pharmacist Interventions

During phase 2, a total of 398 pharmacist interventions were recorded (Table 1). Of these, 366 were related to ordering, of which 362 (99%) were accepted by the physicians. Nearly half (178/389 [46%]) were pharmacist-initiated clarification or correction of a proposed or previous order. These errors included incomplete orders, wrong dose, wrong frequency, inappropriate choice, and duplicate therapy. Examples were a recommendation to reduce the dose of intravenous phenytoin from 300 mg 3 times per day, the correct oral dose, to 100 mg 3 times per day and reduction of the dose of ampicillin administered to a patient with renal failure.

In 100 instances, the pharmacist provided drug use information, most often at the time the decision was being made about whether to order a drug. Examples were education of the house staff on the selection of sedatives in patients receiving ventilatory support and the risk of extrapyramidal adverse effects from excessive doses of droperidol.

The pharmacist recommended alternative therapy in 47 cases, suggesting drugs that were safer or cheaper but equally effective, such as changing from intravenous to oral metoclopromide. Potential problems relating to drug interactions and drug allergies were identified by the pharmacist in 22 cases and use of alternative drugs was recommended.

Thirty-two of the pharmacist interventions did not relate to ordering. Among these, the pharmacist provided special order drugs or approved nonformulary use of a drug in 14 instances, identified 6 previously unrecognized ADEs, and uncovered 12 systems errors in the pharmacy dispensing system. One example of dispensing errors was that a medication was prepared for peripheral intravenous infusion when a smaller volume was required for central administration to minimize fluid load.

COMMENT

In previous studies, we demonstrated that nearly half of preventable ADEs resulted from errors in the prescribing process. [1] Prescribing errors frequently have a cascade effect, causing errors downstream in dispensing or administration. The major cause of prescribing errors was physicians' lack of essential drug and patient information at the time of ordering. [2]

One method of providing such information is computerized physician order entry, which has been shown to reduce the rate of serious medication errors by more than half. [9] Evans et al [10] have demonstrated that a computer-assisted management program for antibiotics can substantially reduce excessive use and misuse of antibiotics as well as reduce length of hospital stay and costs. However, most hospitals do not yet have computerized ordering by physicians, so incorporation of the pharmacist into the patient care team is a more feasible alternative at present, especially in units with high medication use.

We estimated the financial impact of the 66% reduction in ADEs. The cost of an ADE has been estimated at $2000 to $2500 per event in 1993. [11,12] However, the cost of a preventable ADE, one due to an error, was estimated at $4685. [9] For the year 1995, we estimate that 58 ADEs were prevented. At $4685 each, the cost reduction in this single unit would be approximately $270,000 per year. The intervention required no additional resources and represented a different use of the existing pharmacist's time. Rather than spending time checking and correcting orders after they had been sent to the pharmacy, the pharmacist was involved at the time the order was written. While participating in rounds as a member of the patient care team, the pharmacist reduced ADEs both by preventing errors and by intercepting them. He prevented errors by providing information about doses, interactions, indications, and drug alternatives to physicians at the time of ordering. He intercepted errors by immediately reviewing all orders and correcting deficiencies before the orders were transmitted to the pharmacy. In addition, the pharmacist prevented nursing medication errors by providing ready consultation to the nursing staff and teaching drug safety.

Finally, the on-site pharmacist took overall responsibility for medication safety, spotting unsafe conditions and identifying needs for process improvement. For example, during the study period the pharmacist identified 12 systems errors in pharmacy function and 6 ADEs that probably would not have otherwise been discovered.

The presence of the pharmacist on rounds was well accepted by physicians, as evidenced by the fact that 99% of the recommendations were accepted. While staff perceptions were not evaluated systematically, in our experience, nurses also accepted this role easily, appreciating the reduction in extra work, such as telephoning physicians to have orders corrected. The pharmacist in this study had to overcome the traditional impression of the medical staff that pharmacists may be primarily concerned with costs. This academic medical ICU environment had the added challenge of dealing with a new group of house staff, fellows, and attending physicians every few weeks. In ICUs where the attending physicians are permanent and fellows are assigned for many months, acceptance might be enhanced.

Our study has several limitations. We studied only 1 ICU in 1 teaching hospital. Adverse drug events are more common in teaching hospitals than in community hospitals [13] and occur more frequently in ICUs, [1] so these findings are not generalizable to all types of units or all types of hospitals. However, the magnitude of the impact of the pharmacist's presence was so great that a substantial effect would probably be found in ICUs in other hospitals. Second, our results do not represent the full extent of preventable ADEs, since record review does not capture all events, nor does it capture most potential ADEs, the "near misses," because they are seldom recorded in patient charts. Third, physicians and nurses in this ICU function as a team and make rounds together. Pharmacist participation would be more difficult to arrange in units where multiple physicians make rounds at different times. Finally, the success of the pharmacist intervention depends on interpersonal relationships. Thus, the personality and cooperativeness of the pharmacist and the medical staff are critical factors in making this system work, especially at the beginning. Similar prevention of ADEs prompted by a designated ICU pharmacist probably would be less likely to occur in ICUs in which staff are not part of a multidisciplinary team and when ICU staff are not open to the important role that the pharmacist can play in optimizing ICU management.

We conclude that participation of a pharmacist on medical rounds can be a powerful means of reducing the risk of ADEs.

Funding/Support: This study was supported by grants from the Risk Management Foundation, Boston, Mass, and the American Society of Health-System Pharmacists Foundation, Bethesda, Md.

Acknowledgment: We would like to thank Christopher Lyman, RPh, Theresa Gallivan, RN, B. Taylor Thompson, MD, and Barbara Cockerill, MD, for their assistance in the study.

Reprints are not available from the author.

Corresponding Author: Lucian L. Leape, MD, Department of Health Policy and Management, Harvard School of Public Health, 677 Huntington Ave, Boston, MA 02115.

REFERENCES

1. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events implications for prevention. JAMA. 1995;274:29-34. Ovid Full Text Bibliographic Links

2. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. JAMA. 1995;274:35-43. Ovid Full Text Bibliographic Links

3. Folli HL, Poole RL, Benitz WE, Russo JC. Medication error prevention by clinical pharmacists in two children's hospitals. Pediatrics. 1987;79:718-722. Bibliographic Links

4. Broyles JE, Brown RO, Vehe KL, et al. Pharmacist interventions improve fluid balance in fluid restricted patients requiring parenteral nutrition. Ann Pharmacother. 1991;25:119-122.

5. Kilroy RA, Iafrate RP. Provision of pharmaceutical care in the intensive care unit. Crit Care Nurs Clin North Am. 1993;5:221-225. Bibliographic Links

6. Montazeri M, Cook DJ. Impact of a clinical pharmacist in a multidisciplinary intensive care unit. Crit Care Med. 1994;22:1044-1048. Bibliographic Links

7. Bates DW, Leape LL, Petrycki S. Incidence and preventability of adverse drug events in hospitalized adults. J Gen Intern Med. 1993;8:289-294. Bibliographic Links

8. SAS Procedures Guide. Release 6.03. Cary, NC: SAS Institute Inc; 1988.

9. Bates DW, Leape LL, Cullen DJ, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. JAMA. 1998;280:1311-1316. Ovid Full Text Bibliographic Links

10. Evans RS, Pestotnik MA, Classen DC, et al. A computer-assisted management program for antibiotics and other antiinfective agents. N Engl J Med. 1998;338:232-238. Full Text Bibliographic Links

11. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. JAMA. 1997;277:307-311. Ovid Full Text Bibliographic Links

12. Classen DC, Pestotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients. JAMA. 1997; 277:301-306. Ovid Full Text Bibliographic Links

13. Brennan TA, Leape LL, Laird N, et al. Incidence of adverse events and negligence in hospitalized patients. N Engl J Med. 1991;324:370-376. Bibliographic Links

CARING FOR THE CRITICALLY ILL PATIENT (Cook DJ, ed); Intensive Care Units; Medication Errors; Patient Care Team; Pharmacists

---

Accession Number: 00005407-199907210-00006

Impact of a pediatric clinical pharmacist in the pediatric intensive care unit

Marianne I. Krupicka, PharmD; Susan L. Bratton, MD, MPH; Karen Sonnenthal, MS, FNP; Brahm Goldstein, MD, FAAP, FCCM

Objective: To study the impact of a clinical pharmacist in a pediatric intensive care unit. The goals of the study were to determine the type and quantity of patient care interventions recommended by a clinical pharmacist and to specifically examine cost savings (or loss) that resulted from clinical pharmacist recommendations.

Design: A prospective case series.

Setting: Ten-bed pediatric intensive care unit in a university-affiliated children's hospital.

Patients: All patients admitted to the pediatric intensive care unit during the study period.

Interventions: None.

Measurements and Main Results: During the 24-wk study period, the pediatric clinical pharmacist documented all interventions that occurred during her shift. She rounded with the pediatric intensive care unit team approximately two times a week and reviewed medication lists daily. Drug acquisition costs were used to calculate drug cost savings. Demographic information was collected on all the patients in the pediatric intensive care unit during the study period.

There were 35 recommendations per 100 patient days. The most common interventions were dosage changes (28%), drug information (26%), and miscellaneous information (22%). The average time spent per day by the clinical pharmacist in the pediatric intensive care unit was 0.73 hrs or 0.02 full-time equivalent. The total cost direct savings for the study period was $1,977. Extrapolated to direct cost savings per year, the total amount saved was $9,135/year or 0.15 full-time equivalent. Indirect savings from educational activities, avoidance of medication errors, and optimization of medical therapies represent an additional nonquantifiable amount.

Conclusion: We conclude that a clinical pharmacist is an important and cost-effective member of the pediatric intensive care unit team. (Crit Care Med 2002; 30:919–921)

Key Words: pediatric clinical pharmacist; cost savings; pediatric intensive care

In recent years, changes in health care financing have necessitated that health care providers delineate and justify both a medical and an economic basis for their involvement in patient care. Numerous studies have evaluated the role of the clinical pharmacist in adult intensive care units (1–7). Few have addressed the role of the clinical pharmacist in the pediatric intensive care unit (ICU) (8). Our intent was to study the medical and economic impact of a clinical pediatric pharmacist in our pediatric ICU.

The goals of the study were to determine the type and quantity of patient care interventions recommended by a clinical pharmacist and to specifically examine cost savings (or loss) that resulted from clinical pharmacist recommendations in the pediatric ICU. We hypothesized that the pediatric ICU clinical pharmacist would have a positive impact on patient care and medical staff education and would prove to be cost effective.

METHODS

Doernbecher Children's Hospital is a 124-bed comprehensive pediatric hospital, including pediatric intensive care, general medical/surgery, hematology/oncology, and neonatal care units. Pharmacy services are provided 24 hrs a day, 7 days a week from a centralized pharmacy. Clinical pharmacy services are provided directly on the units 5 days a week by a pediatric clinical pharmacist who reviews medication records for all patients. Weekend services are provided in a centralized location. At the time of this study, the pediatric ICU pharmacist (MIK) had worked at the institution as the pediatric clinical pharmacist for approximately 4 yrs.

The study took place in the 10-bed medical/surgical pediatric ICU at Doernbecher Children's Hospital, OR Health Sciences University. The study was approved by the Institutional Review Board. The study was conducted from November 19, 1996, to May 6, 1997, and included 24 consecutive 4-day weeks (79 days), excluding days that the pediatric clinical pharmacist was off duty.

The following data were recorded for all pediatric ICU patients enrolled in the study: subject number, age, gender, daily Pediatric Risk of Mortality Index (PRISM) score (as a measure of severity of illness) (9), and total number and specific type of medications they received. During the study, the pediatric clinical pharmacist (MIK) documented all interventions that occurred during the shift (7:00 am to 3:30 pm) attributable to recommendations made on rounds or from a private discussion with the physicians. The clinical pharmacist attended morning rounds with the pediatric ICU service approximately two times per week.

Drug acquisition costs were used to calculate drug cost savings. Drug acquisition costs were multiplied by 2.4 days of therapy (the average length of stay for pediatric ICU patients) to obtain the total cost savings for discontinued drugs if treatment began on day 1 of the patient's pediatric ICU stay. If the

From the Department of Pharmacy (MIK) and the Division of Pediatric Critical Care (SLB, KS, BG), Department of Pediatrics, Doernbecher Children's Hospital & Oregon Health Sciences University, Portland, OR.

Supported, in part, by a grant from the American Society of Health-System Pharmacists (AHSP) Research and Education Foundation, Bethesda, MD.

Table 1. Selected demographic features of the study population

	Admissions to the PICU With Rx Recommendations (n = 77)	Admissions to the PICU Without Rx Recommendations (n = 138)
Age, yrs, median (25th, 75th quartiles)	5.0 (0.1, 10.5)	3.5 (0.8, 10.7)
Male, n (%)	44 (57)	68 (49)
PRISM Score, median (25th, 75th quartiles)	4 (0, 5)	2.5 (0, 4)
PICU days, median (25th, 75th quartiles)[a]	3 (1, 6)	1 (1, 3)
Total hospital days, median (25th, 75th quartiles)[a]	7 (3, 13)	5 (2, 11)
Pharmacist time in rounds, mins, median (25th, 75th quartiles)[a]	2 (0, 5)	0 (0, 3)
Pharmacist total time in patient care, mins, median (25th, 75th quartiles)[a]	7 (5, 13)	3.5 (2, 6)

PICU, pediatric intensive care unit; PRISM, Pediatric Risk of Mortality Index.
[a]$p < .05$.

patient had already stayed in the pediatric ICU >2.4 days, the cost was calculated for 1 day. If the drug was changed to a more or less expensive counterpart, the difference in drug costs before and after the change was determined. If the more expensive medication was therapeutically superior, then the costs was not added into the calculation. Labor, supplies, or any other indirect costs were not included.

The database was managed by using GraphPad Prism PPC (GraphPad Software, San Diego, CA). Descriptive statistics for the analysis including means, standard deviations, medians, and 25th and 75th quartiles were calculated. Subjects who received at least one recommendation from the pharmacist were compared with those who did not by using the Mann-Whitney U test for continuous data and the chi-square test for categorical data. We also examined correlations between patient diagnosis, severity of illness (PRISM), and total and specific pharmaceutical interventions. Significance was defined as $p < .05$.

RESULTS

Two hundred and one children were admitted to the pediatric ICU during the study days. Twelve were readmitted to the pediatric ICU during the study, and one child was admitted three times during the study days for a total of 215 patient admissions to the pediatric ICU. Children who received recommendations during an admission had significantly longer pediatric ICU stays as well as total hospital stay (Table 1). They also tended to be more severely ill with higher median PRISM scores, although this was not statistically significant. The longer length of stay and PRISM scores suggest that the children with recommendations were more severely ill compared with the children who did not have pharmacy interventions.

As expected, the pharmacist spent significantly more time in both rounds and in total time devoted to a patient in children who received a recommendation compared with those who did not have a recommendation from the pharmacist. Among children who received recommendations from the pharmacist, the median number of recommendations was 1 (25th and 75th quartiles, 1 and2). The groups did not differ significantly by age or gender.

There were 493 total patient days studied. The pharmacist made 172 recommendations for 77 patients either during rounds or when reviewing their medication lists during the study period. There were 35 recommendations per 100 patient days. We found the most common interventions were dosage changes, drug information, and miscellaneous information (Table 2).

The average time spent per day by the clinical pharmacist in the pediatric ICU was 0.73 hrs. The total cost savings for the study period was $1,977. Extrapolated to cost savings per year, the total amount saved was $9,135/year if the pharmacist was employed full-time.

DISCUSSION

This study documents a major educational role for the clinical pharmacist in the pediatric ICU and demonstrates an economic savings from decreases in drug cost. Critically ill patients frequently require multiple drug therapy and may have multiple-system organ dysfunction that alters drug pharmacokinetics and pharmacodynamics. In addition to these challenges, patients in the pediatric ICU have a wide range of age and weight, adding to the complexity of pharmacy interventions compared with adult ICU patients.

Our study demonstrated that changes in drug dosing were the most common interventions that the clinical pharmacist made in our pediatric ICU. The potential medical benefit and economic savings from avoidance of medication error attributable to over- or underdosing, although not possible to accurately calculate, are likely substantial. The presence of a pediatric clinical pharmacist in the pediatric ICU also improved staff education regarding pharmacologic therapy. Two of the most common recommendations involved drug information and general information to the physicians and nurses. Other reports on activities of a clinical pharmacist in adult ICUs also confirm the importance of staff education (10–11).

We found that even in a relatively small pediatric ICU (average census during the study, 4.9 patients), interventions by the clinical pharmacist resulted in substantial drug costs savings and provided the medical staff with important drug education. The average time spent per day was <1 hr, allowing the pharmacist time to attend to other duties.

The cost savings that we estimated are conservative because discontinued medication costs were calculated on 24-hr supply of drug: labor, materials, and other cost savings were not included. Furthermore, improvements in dosing efficiency were not included; the pharmacist did not round daily with the service (although the pharmacist did review patient medications daily), and the cost of errors that were avoided could not be accurately estimated. Even so, our results suggest that the direct cost savings from the pediatric ICU pharmacist activities may account for up to 0.15 full-time equivalent of the average starting salary for a hospital-based pharmacist in 1997 ($62,400) (12). This direct amount more than justifies the average time spent in the pediatric ICU of 0.73 hrs/day or 0.02 full-time equivalent. In addition, this calculation does not take into account the potential indirect savings/benefits from the avoidance of medical errors, benefits from ongoing education, and optimization of patient medical therapies. Avoidance of medical errors recently has received intense scrutiny by both the federal government and general public (13–15). Furthermore, the Society of Critical Care Medicine has endorsed the

Table 2. Recommendations from the pharmacist

Interventions	n	%
Change in drug dosing	49	28
Drug information	45	26
Miscellaneous information	38	22
Discontinue drug	18	10
Start new drug	5	3
Change drug	5	3
Order test/drug level	4	2
Identification of actual or potential adverse drug reactions	3	2
Change in dose form or route of administration	2	1
Report adverse drug event	2	1
Cancel laboratory test	1	0.6

need for subspecialty pharmacy expertise in the care of critically ill patients (16).

Our findings are similar to reports of adult ICUs (11, 12) and general medical wards (17–19) that have documented the important educational role of the pharmacist in addition to realized cost savings. Montazeri and Cook (10) reported that 575 interventions occurred over a 3-month period in a 15-bed medical-surgical ICU, resulting in a net savings of $10,010.60 (Canadian). Furthermore, the pharmacist played an important educational function by providing drug information to physicians and nurses. Miyagawa and Rivera (11) studied the impact of a clinical pharmacist in a 14-bed surgical ICU. Over a 13-wk period, a total of 322 interventions to improve drug therapy were made, resulting in an annual cost savings of >$72,000 (11). Another study found that 724 medication errors were averted over a 4-yr period in their ICUs because of pharmacist intervention (17). A more recent, prospective, epidemiologic study in two academic university hospitals found that although the preventable adverse drug event rate in children was similar to that of a previous adult hospital study, the potential adverse drug event rate was three-fold higher (15). Physician reviewers judged that ward-based clinical pharmacists could have prevented 94% of potential adverse drug events (15)

The activities of critical care pharmacists are expanding and evolving (6, 20). Critical care pharmacists in many institutions no longer primarily function in roles of drug preparation and dispensing. The new focuses are on monitoring drug dosages and interactions, making recommendations to the physician staff regarding changes in medication therapy, and developing pharmacotherapeutic plans to optimize drug therapy for ICU patients and avoid adverse medication interactions and errors (15).

There are a number of limitations to this study. First, although it was prospectively designed, it was not a controlled trial so there is no control population. Thus, benefits need be assumed rather than proven as causal. We have taken care to provide conservative estimates when required. Second, the patients' clinical course was not factored into the potential savings or expenditures as a result of the pharmacist's interventions. Third, we have no direct evidence of positive or lasting impact on medical staff education, only intuitive assumptions based on changes made in care. Fourth, it is possible that bias was introduced as a result of the clinical pharmacist being one of the authors (MIK), although this seems unlikely.

Even taking into account these real and potential limitations, we suggest that the results from this study are valid taken within the context of the study design. Our results add to the growing body of evidence that supports the use, safety, and cost-effectiveness of a clinical ICU pharmacist. It is clear that additional economically sophisticated studies are required to more completely evaluate the role of the clinical pharmacist in the ICU.

REFERENCES

1. ASHP supplemental standard and learning objectives for residency training in pediatric pharmacy practice. *In:* Practice Standards of ASHP 1995–96. Hickes WE (Ed). Bethesda, MD, American Society of Hospital Pharmacists, 1995
2. Hepler CD, Strand LM: Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990; 47:533–543
3. American Society of Hospital Pharmacists: ASHP statement on the pharmacist's clinical role in the organized health care setting. *Am J Hosp Pharm* 1989; 46:2345–2346
4. Folli HI, Poole RL, Benitx WE, et al: Medication error prevention by clinical pharmacists in two children's hospitals. *Am J Hosp Pharm* 1993; 50:305–314
5. American Society of Hospital Pharmacists: ASHP guidelines for providing pediatric pharmaceutical services in organized health care systems. *Am J Hosp Pharm* 1994; 51: 1690–1692
6. Lal LS, Anassi EO, McCants E: Documentation of the first steps of pediatric pharmaceutical care in a country hospital. *Hosp Pharm* 1995; 30:1107–1108
7. Hutchinson RA, Schumock GT: Need to develop a legal and ethical base for pharmaceutical care. *Ann Pharmacother* 1994; 28: 954–956
8. Flack KA, Darsey EH, Naughton MJ: Pharmacy interventions in a multidisciplinary pediatric intensive care unit. *J Pediatr Pharm Pract* 1997; 3:162–167
9. Pollack M, Ruttimann UK, Getson PR: Predictive risk of mortality (PRISM) score. *Crit Care Med* 1988; 16:1110–1116
10. Montazeri M, Cook DJ: Impact of a clinical pharmacist in a multidisciplinary intensive care unit. *Crit Care Med* 1994; 22: 1044–1048
11. Miyagawa CI, Rivera JO: Effect of pharmacist interventions on drug therapy costs in a surgical intensive-care unit. *Am J Hosp Pharm* 1986; 43:3008–3013
12. Pharmacy Salary Review. Available at: http://208.155.43.155/candidates/article.asp?sessionID=YJKSHERD&article_id=32. Accessed May 7, 2001
13. For Want of Soap and Water. *New York Times* March 27, 2000
14. Institute of Medicine: To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS (Eds). Washington, DC, National Academy Press, 2000
15. Kaushal R, Bates DW, Landrigan C, et al: Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001; 285: 2114–2120
16. Rudis MI, Brandl KM, for the Society of Critical Care Medicine and American College of Clinical Pharmacy Task Force on Critical Care Pharmacy Services: Position paper on critical care pharmacy services. *Crit Care Med* 2000; 28: 3746–3750
17. Kilroy RA, Iafrate RP: Provision of pharmaceutical care in the intensive care unit. *Crit Care Nurs Clin N Am* 1993; 5:221–225
18. Haig GM, Kiser LA: Effect of pharmacist participation on a medical team on costs, charges, and length of stay. *Am J Hosp Pharm* 1991; 48:1457–1462
19. Bjornson DC, Hiner WO, Potyk RP, et al: Effect of pharmacists on health care outcomes in hospitalized patients. *Am J Hosp Pharm* 1993; 50:1875–1884
20. Dasta JF, Anagaran DM: Evolving role of the pharmacist in critical care. *Crit Care Med* 1992; 20:563–565

Insp Fac 4 5/12

Attachment 6

Susan Ravnan

From: shane@cshs.org
Sent: Tuesday, January 17, 2006 3:33 PM
To: shane@cshs.org; Susan Ravnan
Subject: Medication Prescribing Errors in a Teaching Hospital

84

Ovid Technologies, Inc. Email Service

Results: Archives of Internal Medicine

Volume 157(14), 28 July 1997, pp 1569-1576

Medication-Prescribing Errors in a Teaching Hospital: A 9-Year Experience [Original Investigation]

Lesar, Timothy S. PharmD; Lomaestro, Ben M. PharmD; Pohl, Henry MD
From the Albany Medical Center, Albany, NY. (Lesar, Lomaestro, Pohl).

Outline

Graphics

Abstract

Background: Improved understanding of medication-prescribing errors should be useful in the design of error prevention strategies.

Objective: To report analysis of a 9-year experience with a systematic program of detecting, recording, and evaluating medication-prescribing errors in a teaching hospital.

: All medication-prescribing errors with potential for adverse patient outcome detected and averted by staff pharmacists from January 1, 1987, through December 31, 1995, were systematically recorded and analyzed. Errors were evaluated by type of error, medication class involved, prescribing service, potential severity, time of day, and month. Data were analyzed to determine changes in medication-prescribing error frequency and characteristics occurring during the 9-year study period.

: A total of 11 186 confirmed medication-prescribing errors with potential for adverse patient consequences were detected and averted during the study period. The annual number of errors detected increased from 522 in the index year 1987 to 2115 in 1995. The rate of errors occurring per order written, per admission, and per patient-day, all increased significantly during the study duration (P

Conclusions: The results of this study suggest there may exist a progressively increasing risk of adverse drug events for hospitalized patients. The increased rate of errors is possibly associated with increases in the intensity of medical care and use of drug therapy. Limited changes in the characteristics of prescribing errors occurred, as similar type errors were found to be repeated with increasing frequency. New errors were encountered as new drug therapies were introduced. Health care practitioners and health care systems must incorporate adequate error reduction, prevention, and detection mechanisms into the routine provision of care.

Arch Intern Med.1997;157:1569-1576

DRUG THERAPY is the most common type of therapeutic intervention made in the treatment of patients. Despite the excellent benefits and safety profile of most medications, adverse drug events pose a significant risk to patients. [1-3] Many adverse drug events are preventable, and among the preventable causes of adverse drug events, errors in the prescribing or management of drug therapy are the most common. [3-10] Recent changes in the provision of medical care in hospitals, such as increased intensity of care, increased use of medications, and availability of new drug therapies, potentially increase risks to patients for iatrogenic adverse drug events. Little or no data are available to determine if patients are now at a higher risk for such adverse events. As errors and deficiencies in medication prescribing and management are the most common cause of medication-related adverse events, [3-7] the tracking of the frequency and characteristics of prescribing errors should provide information regarding the impact of health care provision changes on patient risk for subsequent adverse events. The frequency and nature of prescribing errors were first systematically studied in the late 1980s, [7-9,11] but the effects of changes in health care on errors have not been reported.

In 1987, a program of detecting, evaluating, classifying, rating, and recording medication-prescribing errors and problems was implemented in a tertiary care teaching hospital. [9] This database was evaluated to better characterize the nature of prescribing errors and to determine if any changes in the frequency and characteristics of such errors occurred during 1987 through 1995.

METHODS

The study was conducted in a tertiary care teaching hospital located in northeastern New York State. Study data were concurrently collected from January 1, 1987, through December 31, 1995. Data from the index year 1987 [9] and select data from 1994 through 1995 [10] have been previously published. Total bed capacity for the hospital ranged from 631 to 674 beds during the study period. Approximate major bed allocations included 340 to 360 medical or surgical beds, 51 to 64 adult intensive care beds, 52 psychiatric beds, 20 rehabilitation beds, 61 pediatric beds, and a 35- to 50-bed neonate intensive care unit. The prescribing medical staff consisted of house staff, fellows, and attending physicians from the associated medical school as well as physicians from the surrounding community with admitting privileges.

Confirmed medication-prescribing errors detected by staff pharmacists were obtained, evaluated, and recorded as previously described. [9,10] All medication orders either written by or cosigned by a physician during the study period were included in the study. Medication orders were either handwritten by the prescriber on standard blank physician order sheets or in the form of preprinted forms requiring partial completion and signature. Copies of the original orders were sent to the pharmacy via facsimile or via pneumatic tube. All medication orders were reviewed and entered into the pharmacy computer system by staff pharmacists prior to dispensing. Pharmacists routinely used any available information sources to evaluate all medication orders for appropriateness. Following the identification of medication orders potentially in error, the pharmacist contacted the prescriber or a cross-covering physician to obtain additional information and to discuss the order. Potential prescribing problems were defined as medication orders that involved the wrong patient, drug, dose, dosing frequency, route, or dosage form; inappropriate indication for use; inappropriate combinations of drugs; documented allergies to ordered medications; contraindicated therapy; missing critical information; and other miscellaneous problems. The medication order(s) in question was confirmed as written, clarified, changed, or discontinued following the discussion between the pharmacist and physician. All identified problem orders that were jointly determined by the physician and pharmacist to require correction and subsequently changed were considered confirmed problem orders. All confirmed medication-prescribing problems were further reviewed by a clinical pharmacist within 24 hours and by one of us (T.S.L.) within 72 hours. Further information was obtained or actions taken to fully understand the problem and ensure appropriate drug therapy was provided. Problem orders that were determined by this secondary review to be in error were then defined as confirmed medication-prescribing errors.

Assessment of potential adverse outcome of each error was based on available patient and pharmacological information regarding risk for adverse events. The significance of each error was based on the potential of the error to be carried out (ie, orders that were unlikely to be carried out because of product characteristics, physical and mechanical factors, or the drug distribution and preparation processes of the hospital were not considered significant) and, if carried out as ordered, to result in adverse consequences, either an increased risk of adverse effects or an inadequate therapeutic response. The potential significance of errant orders was evaluated using a previously described rating scale. [9,10] Consistency and agreement of assigning an error severity classification to specific errors has been previously reported. [10] Additional verification of consistency and agreement of assigning an error severity classification to specific errors was determined by review of 500 consecutive errors rated as A, B, or C occurring in the last study year by a physician and 2 pharmacists. Only those errors classified as significant A, B, or C (ie, errors with at least a significant potential to produce an adverse patient outcome) were included in this study.

The number of hospital admissions, length of stay, and number of patient-days were obtained from hospital utilization statistics. The number of medication orders written per time of day, per month, and per year were obtained from the pharmacy computer database. The percentage of medication orders written for each medication class and prescribing service in 1995 was determined by manual count of 10 000 medication orders.

The statistical significance of between-group differences in error rates was determined by chi squared analysis; the significance of trends was determined by chi squared for trends. Correlation of the rate of prescribing errors to patient care activities was determined using regression analysis. The measure of association between raters was determined using Cohen kappa statistic.

RESULTS

A total of 11 186 medication-prescribing errors rated as having potential for adverse patient effects were detected during the 9-year study period. The number of significant errors detected per year increased from 522 in 1987 to 2115 in 1995 (Table 1). The overall clinically significant error rates for the study period were 2.87 errors per 1000 medication orders, 6.52 errors per 1000 patient-days, and 5.29 errors per 100 admissions. Error rates per medication order written, per hospital admission, and per patient-days provided all demonstrated a significant increase from 1987 to 1995 (P

Table 1. Hospital Activity and Prescribing Errors for 1987 Through 1995

Figure 1. Total and severe and serious prescribing error rates for 1987 through 1995.

The potential significance of detected prescribing errors varied from serious life-threatening reactions to minor, reversible adverse effects. Of the 11 186 errors, the potential severity of adverse outcomes of 2093 (18.2%) were rated as potentially fatal, severe, or serious (class A or B). The rate of serious errors per 100 hospital admissions, per 1000 patient-days, and per 1000 medication orders written increased during the study period but did not demonstrate a significant trend (P>.05) (Figure 1).

The drug classes most commonly involved in medication order errors were antimicrobials (34.1%), cardiovascular agents (15.9%), gastrointestinal agents (7%), narcotic analgesics (5.7%), hormonal agents (4.1%), and nonnarcotic analgesics and nonsteroidal anti-inflammatory drugs (4.9%) (Table 2). Errors involving cardiovascular agents and those involving benzodiazepines demonstrated the most consistent change in frequency during the study period. Errors involving cardiovascular agents increased progressively during the study period, from 10.7% to more than 18% of total errors (P.25).

Table 2. Medication Class Involved in Prescribing Errors for 1987 Through 1995

Figure 2. Prescribing error rates per medication orders written for each medication class in 1995.

Dosing errors (56.1%, total overdoses and underdoses), prescribing drugs to which the patient had a documented allergy (14.4%), and prescribing inappropriate dosage forms (11.2%) were the most common types of errors detected (Figure 3). The proportion of errors attributable to prescribing an inappropriate dosage form demonstrated the greatest and most consistent change during the study period, increasing from 3.6% of errors in 1987 to more than 12% of errors in 1993 and thereafter (P

Figure 3. Type of medication-prescribing errors as percentage of total overall for 1987 through 1995.

Table 3. Medication Error Types for 1987 Through 1995

The frequency of a medication class being involved in an error varied with the type of error. Overdoses most commonly involved antimicrobials (32.3%), gastrointestinal agents (10.8%), cardiovascular agents (10.1%), and hormonal agents (8.2%), while underdoses most commonly involved antibiotics (49.3%), cardiovascular agents (12.9%), and vitamins, minerals, and electrolytes (5.1%), and allergies most commonly involved antimicrobials (55.2%), opiates and narcotic analgesics (33.4%), and nonsteroidal anti-inflammatory drugs (8.1%). Dosage form errors most commonly involved cardiovascular agents (67%) and xanthines (15.5%). Serious and severe errors (class A or B) were most frequently caused by prescribing a drug to which the patient had a documented allergy (45.2%), overdose (26.3%), underdose (12.1%), and prescribing the wrong drug (5.5%).

Overall, the most common errors involved overdose antimicrobials (12%), underdose of antimicrobials (9.4%), allergies to antimicrobials (8%), wrong dosage form for cardiovascular agents (6.8%), allergies to opiates and narcotic analgesics (4.9%), overdose of gastrointestinal agent (4%), overdose of cardiovascular agents (3.6%), overdose of vitamins, minerals, and electrolytes (3%), duplication of antimicrobial therapy (2.6%), and underdose of cardiovascular agents (2.4%).

The rate of prescribing errors per 1000 medication orders written in 1995 differed between prescribing service (P

Figure 4. Prescribing error rates per 1000 medication orders written for each prescribing service in 1995.

Table 4. Number of Errors and Percentage of Yearly Errors Associated With Each Attending Service

---

Figure 5. Errors per 100 admissions (A) and per 1000 patient-days (B) for prescribing services for 1987 through 1995. Ob/Gyn indicates obstetrics and gynecology.

The time of day orders were written could be determined in 9452 errors (84.5%) and 1833 serious errors (87.6%). The highest percentage of errant orders was written between noon and 4 PM, which was consistent with the highest percentage of orders being written during that period. The total and severe and serious error rate per 1000 medication orders written varied with the time of day (P

The error rate per 1000 orders varied significantly by month (P

Of the 500 errors reviewed for consistency of assigning severity ratings, all reviewers agreed on the ratings in 485 (97%). In 8 (54%) of the 15 errors for which disagreement occurred, reviewers considered the error to be of greater severity than that which was initially assigned. Two or more reviewers agreed on 497 (99.5%) of the assigned error severity ratings. Agreement between reviewers as determined by kappa statistic (0.96, P

COMMENT

Our study tracked the frequency and characteristics of medication-prescribing errors during a 9-year period during which significant changes in the provision of medical care in hospitals occurred. The results demonstrate an increasing frequency of medication-prescribing errors detected during this period. Although all reported prescribing errors were averted prior to administration, these findings raise concerns regarding the risk to patients for adverse drug events as a consequence of such errors. Changes in the provision and intensity of medical care provided in hospitals may have contributed to these findings.

Medication errors, adverse events, and other drug-related problems are well-recognized causes of adverse patient outcomes in hospitalized and nonhospitalized patients. [1-7] The Harvard Medical Practice Study [1,2] reported medications to be the single most common cause of adverse events in hospitalized patients, accounting for 19% of all such events. Adverse drug events occur in 6.5% of hospital admissions, [3] and 1% of patients suffer disabling injuries related to drugs. [1,2] Medication-prescribing errors and drug therapy management errors and deficiencies are well-recognized causes of preventable adverse drug events, accounting for half of all such events and potential adverse events in hospitals. [3,5-7,12-20] Additionally, errors occur outside the inpatient setting. A number of reports [21-23] have documented an error frequency of 15% to 18% for discharge prescriptions and that 38% of discharged patients receive at least 1 prescription containing an error. Medication-prescribing errors detected by community pharmacists occur at a rate of 1.4% to 3.2%, with more than 28% of such errors considered potentially harmful. [24] Studies have also revealed frequent drug-related problems in nursing home patients resulting from inappropriate prescribing. [25,26] Drug-related problems are estimated to result in as much as 5% to 10% of hospitalizations. [27] It is possible that a large portion of these admissions are the result of prescription errors and subsequent drug-related adverse events.

CHARACTERISTICS OF AVERTED PRESCRIBING ERRORS

While no adverse events occurred because of the errors reported in this study, the characteristics of the errors (medications involved and types of errors) are consistent with those medications and types of errors associated with eventual adverse patient outcomes [1-7,13,14,19,20] and support the concept that prescribing errors are a frequent and important contributor to preventable adverse drug events. Dosing errors and prescribing medications to which the patient was allergic were the most common types of errors found in this study and in a recent study [5] of adverse drug events. Likewise, antimicrobials, cardiovascular agents, and analgesics were found to be medication classes frequently associated with adverse drug events. [3,7]

Both the type of errors and the drugs involved in errant orders remained relatively constant during the study period, simply increasing in numbers detected. This finding of repeatedly detecting similar errors is consistent with previous studies. [5,28] When changes in error patterns occurred, these changes were consistent with change in patient care practices. A progressive increase in errors involving cardiovascular agents and those involving dosage forms coincided with the rapid proliferation of sustained release (particularly cardiovascular agents) products after 1987. [29] Likewise, the reduction in the number of errors involving benzodiazepines coincided with reduced use of these agents following the implementation of a triplicate prescription requirement for benzodiazepines in New York State. [30] When prescribing errors involved new drug therapies or regimens, these new errors occurred repeatedly, and often predictably. [31-37] Our experience suggests that as new drug therapies are introduced, errors that are either similar to those occurring with older agents or new types of errors resulting from unique characteristics of the drug therapy (ie, dose, route, frequency, name, or dosage form) will also occur with these agents. [10] As more patients are prescribed more medications, more errors will occur; fortunately, the consistency and frequent predictability in the types of errors detected suggest that educational, technological (particularly computerization), and organizational changes should be successful in reducing the frequency of common errors in prescribing. [31,32]

The errors detected in this study are most likely a minimum estimate of the problem of prescribing errors and drug therapy management deficiencies. A lack of adequate patient-specific information limits the ability of centralized staff pharmacists to fully evaluate the appropriateness of drug therapy for an individual patient. Despite the limitations of error detection by pharmacists, studies of adverse drug events and errors using comprehensive chart review and staff interviews [3-5,7] report similar rates of prescribing errors. For consistency, we did not include prescribing errors detected by decentralized clinical pharmacists who are more likely to identify drug-related problems because of greater access to patient information, nurses, and physicians, nor did we include errors detected by nurses, physicians, patients, or other health care providers. Other errors surely went undetected and unreported, and still other errors were detected only after an adverse event occurred and was investigated.

FACTORS CONTRIBUTING TO PRESCRIBING ERRORS

A number of factors are likely contributors to the finding of increased medication-prescribing errors. One factor may be changes in the provision of hospital care. With more admissions and shortened lengths of stay (decreasing from an average of 9.7 days in 1987 to 7.4 days in 1995, at the study hospital), the intensity of medical care provided during each day of hospitalization is increased. The increased intensity of care is reflected by the 2-fold increase in the average number of medication orders per patient-day during the 9-year study period. The finding of an increase in the number of errors per medication order written is consistent with previous studies that found higher error rates to be associated with a higher number of medications being used. [4] The increase in errors occurring per patient-day provided is a result of an increased error rate combined with more medication orders for each patient per day. Increased medication error rates and number of medication orders per admission lead to the increased number of medication errors per patient admitted. Greater intensity of care and increased medication use decreases the time available to prescribers to consider drug therapy issues prior to prescribing. Additionally, less time is available to ensure appropriate monitoring of therapy once initiated. Possibly, this leads to an increased risk for prescribing errors and inadequate management of drug therapy.

While external factors such as increased workload and intensity of care are recognizable contributors to errors, internal causes such as inadequate prescriber knowledge of medications and drug therapies, inadequate performance in managing drug therapy, failure to appreciate the potential consequences of prescribing errors, and performance errors and mental slips are also important contributors. [5,31,32] Likely contributors to increased error rates are the increasing number of new medications available to prescribers, the increased use of nontraditional routes of administration and dosage regimens, and increasingly complex drug regimens. [10,34-36] The Food and Drug Administration approved approximately 225 new medications and numerous new dosage forms and dosage regimens during 1987 through 1995. Additionally, novel, nonapproved uses of drugs may represent an even greater number of new or unusual therapies prescribers will encounter. It is difficult, if not impossible, for physicians to maintain a working knowledge of all the medications they will prescribe and monitor in hospitalized patients. Errors, originating from any cause, are also more likely to go unrecognized by prescribers because of a lack of knowledge required to recognize an errant order as being wrong or the presence of an adverse drug event.

A possible factor contributing to the observed increase in errors was an increased awareness, expertise, and emphasis of the pharmacy staff in evaluating medication orders and patient characteristics following our initial findings in 1987. This may have resulted in a greater effectiveness in detecting errors. Additionally, improved pharmacist detection of errors may have resulted in increased reliance of prescribers on the pharmacy to detect and avert their errors. However, this does not explain the sharp increase in errors detected in 1992 and thereafter.

IMPLICATIONS FOR PREVENTION OF ADVERSE DRUG EVENTS

Efforts to reduce the frequency of adverse drug events should focus on preventable causes of these events. Approximately 30% to 50% of all adverse drug events are preventable, and prescribing errors are by their very nature preventable. Since prescribing errors and suboptimal drug therapy management are responsible for the majority of preventable adverse events, [3-5,7,10,38-45] targeting these errors should be a highly efficient method of reducing patient risk. Both knowledge and performance errors are likely to be amenable to organizational and institutional changes, including computerization, policy and procedure changes, environment improvements, increased standardization of care, workload and scheduling controls, and, in particular, the development of appropriate double-check mechanisms. [32] Technological advances, particularly computerization of medication ordering, should reduce the frequency of many, but not all, the types of prescribing errors reported in this study. [3-5,7,32,46-48] However, technological advances will not prevent all errors, and technological changes will themselves contribute to new types of errors when poorly designed, poorly implemented, or allowed to be circumvented. [49,50]

Improving the availability of pharmacists, and overall pharmacy services, has been recommended to improve the use of medications, [3,5,10] and an association between the level of pharmacy services and reduced length of stay and mortality [51-54] has been demonstrated. Reduction in the number of adverse drug reactions through detection of prescribing errors, as reported in this study, is one possible contributor to these findings. Pharmaceutical firms and the Food and Drug Administration must more carefully consider drug product nomenclature, packaging, and promotion to reduce the chance for errors and to promote appropriate use. Pharmaceutical firms should proactively determine preventable causes of adverse events associated with their products and make appropriate changes in the product, packaging, labeling, and promotion. [31,44,45] Patients can reduce their risk for errors through appropriate and accurate communication with their health care providers concerning their medication history. Likewise, caregivers must more effectively provide information to the patient and family. Improved patient knowledge of medications and disease states will improve the chance that errors and adverse events are averted or minimized.

Given the frequency and multiple causes of medication-prescribing errors, substantial reduction in the number of resultant adverse drug events will require the implementation of a number of these recommendations. Given the high human and monetary cost of adverse drug events, [55,56] implementation of effective preventive measures should be considered a necessity. As the provision of medical care continues to evolve, the potential for increased risk to patients from iatrogenic causes must be evaluated and appropriate risk reduction mechanisms proactively implemented.

A total of 11 186 medication-prescribing errors with potential to result in adverse patient effects were detected during 9 years. The rate of errors increased significantly during the study period and correlated with the increased number of admissions. The results were characterized by an increased occurrence of similar errors. New errors occurred as new medications and therapies were introduced. These findings raise concerns regarding an increasing risk to patients for adverse drug events as a result of prescribing errors. Changes in the provision of care to hospitalized patients possibly contributed to the increased frequency of error and further emphasize the need for improved efforts to reduce the risk of iatrogenic illness from medications.

Accepted for publication January 2, 1997.

We acknowledge the expertise and efforts of the staff pharmacists at Albany Medical Center, Albany, NY.

Reprints: Timothy S. Lesar, PharmD, Albany Medical Center A-85, 43 New Scotland Ave, Albany, NY 12208.

REFERENCES

1. Brennan TA, Leape LL, Laird N, et al. Incidence of adverse effects and negligence in hospitalized patients: results of the Harvard Medical Practice Study I.. N Engl J Med. 1991;324:370-376. Bibliographic Links

2. Leape LL, Brennan T, Laird L, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324:377-384. Bibliographic Links

3. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. JAMA. 1995;274:29-34. Ovid Full Text Bibliographic Links

4. Bates DW, Leape LL, Petrycki S. Incidence and preventability of adverse events in hospitalized patients. J Gen Intern Med. 1993;8:289-294. Bibliographic Links

5. Leape LL, Bates DWE, Cullen DJ, et al. Systems analysis of adverse drug events. JAMA. 1995;274:35-43. Ovid Full Text Bibliographic Links

6. Ferner RE, Whittington RM. Coroner's cases of death due to errors in prescribing or giving medicines or to adverse drug reactions: Birmingham 1986-1991.J R Soc Med. 1994;87:145-148.

7. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape LL. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995;10:199-205. Bibliographic Links

8. Folli HL, Poole RL, Benitz WE, Russo JC. Medication error prevention by clinical pharmacists in two childrens hospitals. Pediatrics. 1987;19:719-722.

9. Lesar TS, Briceland LL, Delcoure K, et al. Medication prescribing errors in a teaching hospital. JAMA. 1990;263:2329-2334. Bibliographic Links

10. Lesar TS, Briceland LL, Stein D. Analysis of factors related to medication prescribing errors. JAMA. 1997;277:312-317.

11. Blum KV, Abel SR, Urbanski CJ, Pierce JM. Medication error prevention by pharmacists. Am J Hosp Pharm. 1988;45:1902-1903. Bibliographic Links

12. Steel K, Gertman PM, Crescenzi C, Anderson J. Iatrogenic illness on a general medical service at a university hospital. N Engl J Med. 1981;304:638-642. Bibliographic Links

13. Medication Error Study. Philadelphia, Pa: Physicians Insurers Association of America; 1993.

14. Dubois RW, Brook RH. Preventable deaths: who, how often, why? Ann Intern Med. 1988;109:582-589. Bibliographic Links

15. Schiff GD, Hegde HK, LaCloche L, Hryhorczuk DO. Inpatient theophylline toxicity: preventable factors. Ann Intern Med. 1991;114:748-753. Bibliographic Links

16. Greenberger PA, Cranberg JA, Ganz M, Hubler GL. A prospective evaluation of elevated serum theophylline concentrations to determine if high concentrations are predictable. Am J Med. 1991;91:67-73. Bibliographic Links

17. Wu AW, Folkman S, McPhee S, Lo B. Do house officers learn from their mistakes? JAMA. 1991;265:2089-2094. Bibliographic Links

18. Vincer MJ, Murray JM, Yuill A, Allen A, Evans J, Stinson D. Drug errors and incidents in a neonatal intensive care unit. AJDC. 1989;143:737-740. Bibliographic Links

19. Edgar TA, Le DS, Cousins DD. Experience with a national medication error reporting program. Am J Hosp Pharm. 1994;51:1335-1338. Bibliographic Links

20. Pearson TF, Pittman DG, Lonley JM, Grapes T, Vigliotti DJ, Mullis SR. Factors associated with preventable adverse drug reactions. Am J Hosp Pharm. 1994;51:2268-2272. Bibliographic Links

21. Schumock GT, Guenette AJ, Keys TW, Hutchinson RW. Prescribing errors for patients about to be discharged from a university teaching hospital. Am J Hosp Pharm. 1994;51:2288-2290. Bibliographic Links

22. Morrill GB, Barreuther C. Screening discharge prescriptions. Am J Hosp Pharm. 1988;45:1904-1905. Bibliographic Links

23. Chan CY, Maxwell PR, Koger CA, Gamboa CD, Brewer JG. Screening discharge prescriptions on a pediatric ward. Am J Hosp Pharm. 1990;47:2060-2061. Bibliographic Links

24. Rupp MT, DeYoung M, Schondelmeyer SW. Prescribing problems and pharmacists interactions in community practice. Med Care. 1992;30:926-940.

25. Beers MH, Ouslander JG, Fingold SF, et al. Inappropriate medication prescribing in skilled nursing facilities. Ann Intern Med. 1992;117:684-689. Bibliographic Links

26. Ray WA, Griffin MR, Schaffner W, Baugh DK, Melton J. Psychotropic drug use and the risk of hip fracture. N Engl J Med. 1987;316:363-369. Bibliographic Links

27. Einerson TR. Drug related hospital admissions. Ann Pharmacother. 1993;27:832-840.

28. Hawkey CJ, Hodgson S, Norman A, Daneshmend TK, Garner ST. Effect of reactive pharmacy intervention on quality of hospital prescribing. BMJ. 1990;300:986-990. Bibliographic Links

29. Epstein M. Calcium antagonists should continue to be used for first-line treatment of hypertension. Arch Intern Med. 1995;155:2150-2156. Ovid Full Text Bibliographic Links

30. Weintraub M, Singh S, Byrne L, Maharaj K, Guttmacher L. Consequences of the 1989 New York State triplicate benzodiazepine prescription regulations. JAMA.

1991;266:2392-2397. Bibliographic Links

31. Vitillo J, Lesar T. Preventing medication prescribing errors. Ann Pharmacother. 1991;25:1388-1394.

32. Leape LL. Error in medicine. JAMA. 1994;272:1851-1857. Ovid Full Text Bibliographic Links

33. Lesar TS. Common prescribing errors. Ann Intern Med. 1992;117:537. Bibliographic Links

34. Lomaestro BL, Lesar TS. Methotrexate prescribing errors. Ann Intern Med. 1992;268:2031-2032.

35. Lesar TS. Standardized dosing tables to reduce errors involving high-dose methylprednisolone for acute spinal cord injury. Hosp Pharm. 1994;29:935-938. Bibliographic Links

36. Lomaestro BL. More on the GUSTO trial. Ann Intern Med. 1994;121:818-819. Ovid Full Text Bibliographic Links

37. Leape LL, Lawthers AG, Brennan TA, Johnson WG. Preventing medical injury. QRB Qual Rev Bull. 1993;19:144-149. Bibliographic Links

38. Classen DC, Pestotnik SL, Evans S, et al. Adverse drug events in hospitalized patients. JAMA. 1997;277:301-306. Ovid Full Text Bibliographic Links

39. Blumenthal D. Making medical errors into 'medical treasures.'JAMA. 1994;272:1867-1868.

40. Kahn KL. Above all 'do no harm:' how shall we avoid errors in medicine? JAMA. 1995;274:75-76. Ovid Full Text Bibliographic Links

41. The science of making mistakes. Lancet. 1995:345:871-872. Editorial.

42. Ferner RE. Is there a cure for drug errors? BMJ. 1995;311:463-464.

43. Leape LL. Preventing adverse drug events. Am J Health Syst Pharm. 1995;52:379-382. Ovid Full Text Bibliographic Links

44. American Society of Hospital Pharmacists. Reports. Draft guidelines on preventable medication errors. Am J Hosp Pharm. 1992;49:640-648. Bibliographic Links

45. American Medical Association Board of Trustees Report. Medication (Drug) Errors in Hospitals. Chicago, Ill: American Medical Association; 1994. Resolution 512, I-93.

46. Johnston ME, Langton KB, Haynes B, Mathieu A. Effects of computer-based clinical decision support systems on clinical performance and patient outcome. Ann Intern Med. 1994;120:135-142. Ovid Full Text Bibliographic Links

47. Bates DW, Kuperman G, Teich JM. Computerized physician order entry and quality of care. Q Manage Health Care. 1994;2:18-27.

48. Bates DW, O'Neil AC, Boyle D, et al. Potential identifiability and preventability of adverse using information systems. J Am Med Inform Assoc. 1994;1:404-411.

49. Wyatt J, Walton R. Computer based prescribing. BMJ. 1995;311:1181-1182. Ovid Full Text Bibliographic Links

50. West DW, Levine S, Magram G, et al. Pediatric medication order error rates related to the mode of order transmission. Arch Pediatr Adolesc Med. 1994;148:1322-1326. Bibliographic Links

51. Pitterle M, Bond C, Raehl C, Franke T. Hospital and pharmacy characteristics

associated with mortality rates in United States hospitals. Pharmacotherapy. 1994;14:620-630. Bibliographic Links

52. Bjornsson DC, Hiner WO, Potyk RP, et al. Effect of pharmacists on health care outcomes in hospitalized patients. Am J Hosp Pharm. 1993;50:1875-1884.

53. McKenney JM, Wasserman AD. Effect of advanced pharmaceutical services on the incidence of adverse drug reactions. Am J Hosp Pharm. 1979;36:1691-1697. Bibliographic Links

54. Haig GM, Kiser LA. Effect of pharmacist participation on a medical team on costs, charges and length of stay. Am J Hosp Pharm. 1991;48:1457-1462. Bibliographic Links

55. Johnson JA, Bootman JL. Drug related morbidity and mortality: a cost of illness model. Arch Intern Med. 1995;155:1949-1956. Ovid Full Text Bibliographic Links

56. Schneider PJ, Gift MG, Lee Y-P, Rothermich EA, Sill BE. Cost of medication related problems at a university hospital. Am J Health Syst Pharm. 1995;52:2415-2418. Ovid Full Text Bibliographic Links

Prescriptions, Drug

Accession Number: 00000779-199707280-00006

Attachment 7

Susan Ravnan

From: Shane, Rita Pharm.D. [Rita.Shane@cshs.org] **Sent:** Tue 1/24/2006 5:08 PM
To: Claudia Foutz; Susan Ravnan
Cc:
Subject: FW: National Pharmacist Shortage, an update
Attachments:

may be of value for state board meeting

> ----------
> From: Saltiel, Emmanuel, Pharm. D.
> Sent: Tuesday, January 24, 2006 12:44 PM
> To: Group Pharmacy Pharmacist
> Subject: National Pharmacist Shortage, an update
>
>
> FYI
>
>
>
> <http://www.medscape.com/viewarticle/521115>
>
> The Pharmacist Shortage: Where Do We Stand?
>
> Charlotte A. Kenreigh, PharmD; Linda Timm Wagner, PharmD
>
> Medscape Pharmacists. 2006;7(1)
>
>
>
>
> A Changing Workforce
>
>
> Seven years ago, the first reports of a significant pharmacist shortage
> began making the news. The shortage was attributed to an increased demand
> for pharmacists and an inability to meet that need. Today, the shortage
> persists even as the pharmacist's role in patient care has expanded far
> beyond the traditional drug-dispensing function.
>
> Professional organizations have been monitoring the pharmacist workforce
> and studying related issues. The Pharmacy Manpower Project (PMP) was
> formed in 1989 to collect, analyze, and distribute data on the supply of
> licensed pharmacists and the demand for their services throughout the
> United States. The PMP is a nonprofit corporation established by national
> pharmacy groups to address workforce issues. By evaluating data from
> monthly surveys of pharmacist employers, the coalition produces the
> Aggregate Demand Index (ADI),[1] a snapshot of the current demand for
> pharmacists and how it has changed over time. National, regional, and
> state demand indices are provided. The National Association of Chain Drug
> Stores (NACDS)[2] and the American Society of Health-System Pharmacists[3]
> also track the supply and demand of pharmacists for their specific areas
> of practice.
>
> Several factors helped contribute to the pharmacist shortage:
> unprecedented increases in the volume of prescriptions (more than a 30%
> increase from 1992 to 1999); growth in the population 65 years or older,
> which uses a disproportionately high share of prescription drugs; greater

> administrative requirements for handling third-party payments, which
> consume 10%-20% of pharmacists' time; and a decline in the number of
> applications to pharmacy schools in the late 1990s, which led to reduced
> class sizes.[4] The downward enrollment trend has now been reversed and
> the number of graduates has increased, but this has created a new problem
> with the greater demand for pharmacy faculty to teach and mentor the
> growing student population.
>
> Using a conservative growth rate of 5% for outpatient prescription orders,
> researchers have calculated that the volume of prescriptions filled in
> 2020 would reach 7.2 billion.[5] The prediction of such historic growth
> does not even reflect the anticipated impact of the aging population,
> making it possible that the prescription volume could actually exceed this
> number.
>
> The composition of the workforce and the nature of pharmacy practice have
> also changed and impacted the shortage. The majority of pharmacists are
> now female; according to studies, women tend to work 6% fewer hours per
> week on average.[5] This could further fuel the shortage.
>
> As the clinical role of pharmacists continues to evolve, the need for more
> pharmacists will continue to rise. Pharmacists are now expected to spend
> more time in face-to-face interactions with patients and with other
> healthcare workers. In addition, the impact of the new Medicare
> prescription benefit on the administrative time required to process
> payments has yet to be realized.
>
>
> What Has Been Done to Address the Shortage?
>
>
> Concerns about a pharmacist shortage have been evident for more than a
> decade. In 1999, Congress mandated a study to explain and address the
> shortage,[6] concluding that simply increasing the number of students
> enrolled in pharmacy programs would not solve the shortage unless it was
> accompanied by an increase in pharmacy faculty and an expansion of the
> educational system. Another important study in 2002 projected a shortfall
> of more than 150,000 pharmacists by 2020,[7] generating much discussion in
> the media.
>
> The Pharmacy Education Aid Act of 2003 was introduced to help increase the
> supply of pharmacists and to increase the educational capacity of the
> nation's colleges of pharmacy. This was the first time the profession
> received this much public attention, and pharmacy leaders hoped that the
> Act would ease the shortage. The bill passed the Senate and was introduced
> in the House of Representatives in late 2003. However, it never became law
> and was cleared from the books after the end of the Congressional
> session.[8]
>
> As it became difficult to fill pharmacist positions across the country,
> pharmacist salaries rose sharply. This trend likely helped promote the
> profession and contributed to an increase in enrollments at pharmacy
> colleges. Enrollments in first professional degree programs for fall 2004
> were up 5.1% from fall 2003, to a total of 43,908.[9]
>
> In fall 2004, 66.5% of enrollees in first professional degree programs
> were females, and almost 60% were white Americans.[9] An
> under-representation of minorities persists, and the percentage of the
> total enrollees actually decreased slightly from 2003 to 2004. A total of

> 8158 first professional degrees (4.8% baccalaureate, 95.2% PharmD) were
> conferred in 2003-04. This reflects an 8.9% increase from 2002-03 and is
> the highest number of first professional pharmacy degrees conferred in the
> past decade since 1998.[9]
>
> To meet expanding enrollments, as many as 10 new schools of pharmacy are
> expected to open by the year 2010, and current pharmacy programs are
> ramping up to meet demand as well.[10] Unfortunately, the ability of these
> programs to effectively meet the need is somewhat hampered by a faculty
> shortage and the ability to recruit and retain faculty.
>
> Some of the pain associated with the pharmacist shortage has been
> addressed by incorporating technological advances into practice sites to
> support the technical functions of the dispensing process. In addition,
> the role of the pharmacy technician has been expanded to give pharmacists
> more time to spend with patients and in review of more complex therapies.
> These trends may also ease the strain of an increased prescription load on
> the current medication use system, but additional pharmacists will
> continue to be needed.
>
> Pharmacy is not the only healthcare profession facing a shortage. Nursing
> is already experiencing a shortage that is expected to continue, and
> physician shortages also are anticipated. In Europe, where shortages have
> already emerged in all of the healthcare professions, increased
> collaboration among providers has blurred traditional professional
> roles.[11] Pharmacists in the United States could see similar changes if
> these shortages persist.
>
>
> Many Positions Remain Unfilled
>
>
> On the basis of the current ADI survey data,[1] a solid majority of states
> (34) are still experiencing some difficulty filling open positions for
> pharmacists. Balanced supply and demand is evident in only 16 states. In
> fact, current survey results indicate that the majority of the US
> population live in areas that report at least a moderately high difficulty
> in filling pharmacist positions.
>
> The American Society of Health-System Pharmacists (ASHP) conducted a
> survey in the summer of 2005 via email. Although the response rate was
> fairly low, the survey uncovered some interesting information.[3] The
> average vacancy rate reported for pharmacist positions was 6.2%. This rate
> reflected an increase from 5% in 2004, but it is lower than the highest
> rate recorded (8.9% in 2000). The pharmacist technician vacancy rate has
> remained steady since 2002, and the current rate 3.9%.
>
> Pharmacy directors were surveyed to determine their perceptions about the
> availability of qualified staff for various pharmacy positions, including
> manager, clinical coordinator, clinical specialist, entry-level and
> experienced frontline pharmacists, and entry-level and experience pharmacy
> technicians.
>
> With the exception of entry-level technicians, pharmacy directors
> indicated high unmet demand for all of the positions. The perception of
> extreme shortage was highest for experienced frontline pharmacists; this
> number rose from 45% in 2004 to 54% in 2005. However, the number is lower
> than the peak in 2002 (67%).
>

> The perception of a shortage in management candidates was especially high,
> up from 74% in 2004 to 84% in 2005. Pharmacy leaders have expressed
> concern that a lack of quality managers could negatively impact the
> profession.
>
> The ASHP survey also found that the average length of time to hire a
> pharmacist has continued to increase, lasting on average about 6.5 months
> in 2005, up from 5.3 in 2004. The average recruiting time was longer in
> rural settings than in suburban settings, at 8.2 months vs 5.6 months,
> respectively.
>
> Another survey, conducted by the National Association of Chain Drug Stores
> Foundation in the summer of 2005, revealed that about 59% of the current
> chain pharmacies participated in the survey.[2] A total of 5971 vacant
> pharmacist positions were reported (4971 full-time and 1000 part-time).
> That number was similar to the January 2005 rate, but higher than rates
> reported since July 2002. The peak vacancy rate for this survey occurred
> in August 2001, with a total of 7743 open positions. It now appears that
> open positions are on the upward trend again.
>
>
> Take-Home Message
>
>
> The shortage of pharmacists continues to be an important issue for
> healthcare. Current data suggest that there are not enough pharmacists to
> meet demands. The silver lining in this situation is that students
> enrolling in schools of pharmacy can expect many job opportunities upon
> graduation for the next several years. Recruitment and retention of
> pharmacy management and faculty remain significant challenges. If pharmacy
> is unable to meet the needs of patients, other healthcare workers could
> step in and assume some of those roles; however, with shortages continuing
> in other healthcare fields as well, the gaps in patient care could
> continue to grow.
>
>
> References
>

> 1.   Aggregate Demand Index. Available at:
> http://www.pharmacymanpower.com/about.html. Accessed January 10, 2006.
>
> 2.   National Association of Chain Drug Stores Foundation. NACDS
> Foundation July 2005 Chain Pharmacy Employment Survey Results. Available
> at:
> http://www.nacds.org/user-assets/PDF_files/July%202005%20Employment%20Surv
> ey.pdf. Accessed January 10, 2006.
>
> 3.   American Society of Health-System Pharmacists. 2005 ASHP
> Pharmacy Staffing Survey. Available at:
> http://www.ashp.org/emplibrary/StaffSurvey2005.pdf. Accessed January 10,
> 2006. 4. American Foundation for Pharmaceutical Education. Facts at a
> Glance: The Pharmacist Shortage. Available at:
> http://www.afpenet.org/news_facts_at_a_glance.htm. Accessed January 10,
> 2006.
>
> 4.   Knapp KK, Quist RM, Walton SM, Miller LM. Update on the
> pharmacist shortage: National and state data through 2003. Am J
> Health-Syst Pharm. 2005;62:492-499.
>

> 5. Health Resources and Services Administration (HRSA), U.S.
> Department of Health and Human Services. The Pharmacist Workforce: A Study
> of the Supply and Demand for Pharmacists. Rockville, Md: HRSA; 2000.
> Available at:
> ftp://ftp.hrsa.gov/bhpr/nationalcenter/pharmacy/pharmstudy.pdf. Accessed
> January 10, 2006.
>
> 6. Knapp DA. Professionally determined need for pharmacy services
> 2020. Am J Pharm Educ. 2002;66:421-429.
>
> 7. H.R. 3591[108]: Pharmacy Education Aid Act of 2003. Available
> at: http://www.govtrack.us/congress/bill.xpd?bill=h108-3591. Accessed
> January 10, 2006.
>
> 8. Patton JM, Mayer AN, Meyer SM. AACP Reports. The pharmacy
> student population: applications received 2003-04, degrees conferred
> 2003-04, Fall 2004 enrollments. Am J Pharm Educ. 2005;69:S15-S29.
>
> 9. American Association of Colleges of Pharmacy. New report reveals
> interest in pharmacy remains high as enrollment continues to grow.
> Available at:
> http://www.aacp.org/site/tertiary.asp?TRACKID=&VID=2&CID=1192&DID=6879.
> Accessed January 10, 2006.
>
> 10. Chi J. Doctor shortage should present R.Ph. opportunities.
> Available at
> http://www.drugtopics.com/drugtopics/content/printContentPopup.jsp?id=184l
> 07. Accessed January 10, 2006.
>
>
>
>
>
>
>

Attachment 8

9

REPORTS

Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes

PETER J. AMBROSE, FRANK G. SAYA, LARRY T. LOVETT, SANDY TAN, DALE W. ADAMS, AND RITA SHANE

Abstract: The accuracy rates of board-registered pharmacy technicians and pharmacists in checking unit dose medication cassettes in the inpatient setting at two separate institutions were examined.

Cedars-Sinai Medical Center and Long Beach Memorial Medical Center, both in Los Angeles county, petitioned the California State Board of Pharmacy to approve a waiver of the California Code of Regulations to conduct an experimental program to compare the accuracy of unit dose medication cassettes checked by pharmacists with that of cassettes checked by trained, certified pharmacy technicians. The study consisted of three parts: assessing pharmacist baseline checking accuracy (Phase I), developing a technician-training program and certifying technicians who completed the didactic and practical training (Phase II), and evaluating the accuracy of certified technicians checking unit dose medication cassettes as a daily function (Phase III).

Twenty-nine pharmacists and 41 technicians (3 of whom were pharmacy interns) participated in the study. Of the technicians, all 41 successfully completed the didactic and practical training; 39 successfully completed the audits and became certified checkers, and 2 (including 1 of the interns) did not complete the certification audits because they were reassigned to another work area or had resigned. In Phase II, the observed accuracy rate and its lower confidence limit exceeded the predetermined minimum requirement of 99.8% for a certified checker. The mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The difference in mean accuracy rates between pharmacists (99.52%; 95% confidence interval [CI] 99.44–99.58%) and technicians (99.89%; 95% CI 99.87–99.90%) was significant ($p < 0.0001$).

Inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

Index terms: Administration; Dispensing; Drug distribution systems; Personnel, pharmacy; Pharmacists, hospital; Pharmacy, institutional, hospital; Professional competence
Am J Health-Syst Pharm. 2002; 59:1183-8

The rapidly changing health care environment necessitates that health care organizations optimize limited resources while improving the quality of care provided. Medication-related complications cost the American health care system as much as $177 billion annually.[1] Pharmacist expertise in drug therapy has repeatedly demonstrated improved patient outcomes, fewer complications, and better control of the cost of medication use.[2-4] However, there currently is a critical shortage of pharmacists, as documented in the Department of Health and Human Services report to Congress on the pharmacist workforce.[5] This shortage is especially acute in California, where the ratio of 58 pharmacists to 100,000 people in the population is well below the national average of 71 pharmacists to 100,000 people in the population. In this same report, the Pharmacy Manpower Project Aggregate Demand Index for California indicated a high

PETER J. AMBROSE, PHARM.D., FASHP, is Clinical Professor, Department of Clinical Pharmacy, School of Pharmacy, University of California San Francisco (UCSF), San Francisco. FRANK G. SAYA, PHARM.D., FASHP, is Manager, Pharmacy Services, Cedars-Sinai Medical Center (CSMC), Los Angeles, CA. LARRY T. LOVETT, PHARM.D., is Manager, ScriptCare Pharmacy, Huntington Beach, CA. SANDY TAN, PHARM.D., is Manager, Pharmacy Services, CSMC. DALE W. ADAMS, PHARM.D., is Vice President, Medical Operations, and Director, Pharmacy Services, Long Beach Memorial Medical Center and Miller Children's Hospital, Long Beach, CA, and Assistant Dean, Department of Clinical Pharmacy, School of Pharmacy, UCSF. RITA SHANE, PHARM.D., FASHP, is Director, Pharmacy Services, CSMC, and Assistant Dean, Department of Clinical Pharmacy, School of Pharmacy, UCSF.

Address correspondence to Dr. Ambrose at the Department of Pharmacy Services, Long Beach Memorial Medical Center, 2801 Atlantic Avenue, P.O. Box 1428, Long Beach, CA 90801-1428.

The contributions of Caroline Chellamy, Pharm.D., Judy Muraszko, Pharm.D., Dennis W. Mackewicz, Pharm.D., Donna Luong, Pharm.D., and the inpatient pharmacy staff at Cedars-Sinai Medical Center and Long Beach Memorial Medical Center are acknowledged.

Presented to the California State Board of Pharmacy, Los Angeles, CA, January 24, 2001.

level of demand for pharmacists. The current shortage of pharmacists poses a significant challenge to providing and maintaining the desired level of pharmaceutical care.[6]

The importance of pharmacy technicians in ensuring the efficient operation of hospital pharmacies is widely recognized. By reassigning nondiscretionary drug distribution tasks to pharmacy technicians, pharmacists can be redeployed to prevent adverse drug events and ensure optimal medication use. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. Pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacist shortage. Expanding the role of technicians by implementing a structured training program with ongoing quality assurance measures may ease the impact of the pharmacist shortage through the judicious and appropriate use of skilled support personnel and increase the time available to pharmacists to perform clinical functions.

Background

In 1997, the California State Board of Pharmacy was petitioned to authorize board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In response to strong opposition from some professional organizations and community pharmacists, who were concerned that the exemption could be expanded outside of the inpatient pharmacy environment and jeopardize pharmacist jobs, the board voted not to grant this petition. However, the board did express a desire to receive additional evidence to further evaluate allowing pharmacy technicians to perform this function. Thus, Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMMC) petitioned the board to grant a waiver of the California Code of Regulations to conduct an "experimental program" under the direction of the University of California, San Francisco, School of Pharmacy. The purpose of the program was to compare the accuracy of unit dose medication cassettes checked by pharmacists with those checked by trained, registered pharmacy technicians in the inpatient setting. In May 1998, the waiver was granted for the experimental program known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The waiver was initially granted through November 1, 2000, and was extended to December 2002 on the basis of data generated from this study, which was presented to the board in January 2001.

CSMC is a 900-bed, acute tertiary care hospital in Los Angeles, California, and LBMMC is a 540-bed, acute tertiary care hospital in Long Beach, California. The unit dose drug distribution system used by CSMC and LBMMC is diagrammed in Figure 1. It should be emphasized that the process of filling and checking unit dose medication cassettes is preceded by the review and verification of all medication orders by a pharmacist. The pharmacist evaluates the appropriateness of the medication, dose, dosage form, route of administration, and frequency in the order and screens for drug allergies, drug–drug interactions, and contraindications. A pharmacist is also responsible for dispensing any initial medication doses needed before the regularly scheduled unit dose cart distribution.

Pharmacy technicians do not evaluate the accuracy and appropriateness of medication orders. Pharmacy technicians perform manipulative and nondiscretionary functions only under the supervision of pharmacists. When filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. Next, a "checker" verifies the filled cassette against the fill list to minimize the possibility of errors before the medications are sent to the nursing areas. In California, only a pharmacist can check these unit dose cassettes, which necessitated the waiver from the board of pharmacy to allow technicians to perform this function in this program. It should be noted that nurses also check the medication when removing it from a patient's cassette and confirm it with the medication administration record (also reviewed and approved by a pharmacist) before administering the medication to the patient, in accordance with Joint Commission on Accreditation of Healthcare Organizations and California Department of Health Services requirements. Thus, a medication is triple-checked before it is administered to a patient.

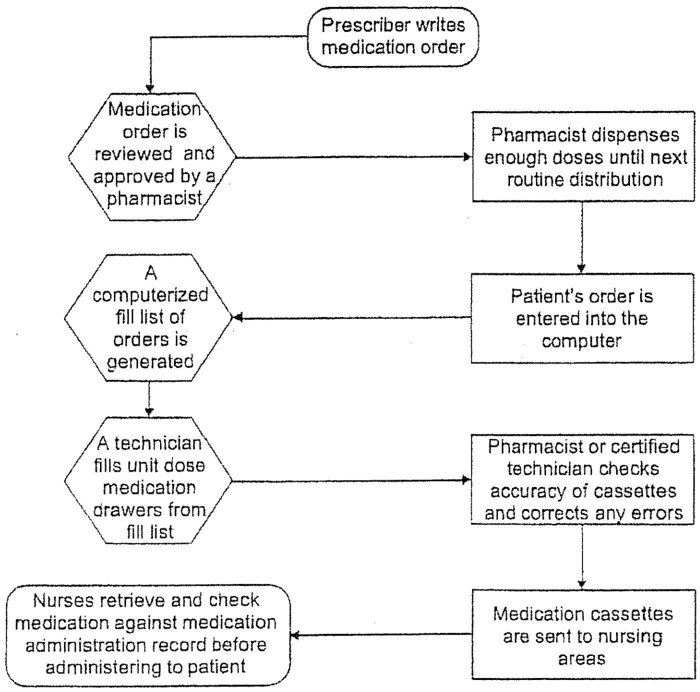
This article describes the experimental program and the accuracy of trained technicians checking unit dose medication cassettes compared with that of pharmacists.

Methods

This study was conducted concurrently at both CSMC and LBMMC and consisted of the following three phases, which were modeled from previous studies[7-13]:

- Phase I: Assessing the baseline accuracy rate of pharmacists checking unit dose medication cassettes,
- Phase II: Developing a technician training program for checking unit dose cassettes and certifying technicians who successfully completed the training program, and

Figure 1. Diagram of the inpatient unit dose drug distribution system used at both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center in normal practice and during the study.



- Phase III: Evaluating the accuracy of certified technicians checking unit dose medication cassettes by conducting quality assurance audits.

Phase I began in June 1998 with the goal of auditing a minimum of 12,500 doses at each institution. Staff pharmacists checked all unit dose cassettes filled by technicians as was the pharmacists' normal routine during the day shift. They were aware that audits were being conducted. Study participants were selected on the basis of their normal work schedules, and no attempt was made to alter assignments. In addition to any spontaneous errors made by technicians filling the cassettes, artificial errors were randomly introduced by pharmacist "auditors" assigned to oversee the study process. Artificial errors were introduced at a rate of at least one error per 500 doses (0.2%) to coincide with a 99.8% minimum accuracy rate.[7] The pharmacist checkers documented and corrected any errors they detected. Subsequently, the pharmacist auditor would audit and verify the accuracy of the pharmacist checker in detecting and correcting artificial and spontaneous filling errors for all doses dispensed during the audit period. Spontaneous and artificial errors overlooked by the pharmacist checkers were documented on an audit form and corrected by the pharmacist auditors before the medication cassettes were distributed to the nursing stations. There were a total of three pharmacists at CSMC and five at LBMMC who were responsible for introducing artificial errors and auditing the pharmacists. In all three phases of the study, an error was defined as a wrong drug, dose, quantity, or dosage form; expired medication; inaccurate concentration; wrong patient's medication cassette; or missing drug.

During Phase II of the program, the pharmacy services departments at CSMC and LBMMC collaborated on a training syllabus, qualifying examination, and data collection forms. Technicians and pharmacy interns (employed and functioning as technicians) were eligible to be included in the study if they were registered with the California State Board of Pharmacy and had at least six months of experience filling unit dose medication cassettes. They were then given didactic and practical training, in accordance with the approach used by the Minnesota Society of Hospital Pharmacists in a pilot project in which technicians were trained to check unit dose cassettes filled by other technicians.[7] The didactic component consisted of lectures on the unit dose process, proper packaging and repackaging techniques, medication safety, and basic pharmaceutical calculations. The didactic training concluded with an examination. Technicians were required to achieve a minimum passing score of 80% on the examination. The practical training included observing a pharmacist checking unit dose cassettes and actual hands-on experience. After successful completion of the didactic and practical training, the technicians were audited for accuracy in checking unit dose cassettes for at least 3500 consecutive doses. Artificial errors, as described for Phase I of the program, were also introduced in this process. The audits were conducted by the same pharmacist auditors as in Phase I. To become a certified technician checker in this program, an overall accuracy rate of at least 99.8% was required. This phase of the study began in June 1998 and was continued as new technicians were trained and included in the program.

Phase III began in April 1999. In this phase, certified technician checkers were responsible for checking unit dose medication cassettes as a daily activity while under the supervision of a pharmacist. Monthly quality assurance audits of at least 500 doses were conducted for each certified technician checker, using the same procedure of introducing random artificial errors as previously described. Accuracy was to be maintained at 99.8% or higher. If a certified technician checker failed a monthly audit, the audit was to be repeated within 30 days. If the technician failed the second audit, the technician would be removed from the checking position until he or she was retrained and recertified. If a certified technician checker did not perform this function for more than three months, an audit would be conducted when the technician restarted checking medication cassettes. If a technician had not checked cassettes for more than six months, recertification was required.

In January 2000, the board approved the following requested amendment to the program: "In Phase III of the study, a monthly audit will be conducted for 3 months, and if the accuracy rate meets or exceeds the minimum target of 99.8% for three consecutive audits, future audits will be conducted quarterly thereafter for that technician. Technicians failing a quarterly audit will have to pass three consecutive monthly audits before resuming quarterly audits." The amendment had been requested by CSMC and LBMMC, since no certified technician had failed a monthly audit.

Error rates were calculated as the number of errors discovered by the auditors divided by the total number of unit doses audited. The accuracy rate was defined as one minus the error rate, which was then converted to a percentage. The 95% confidence intervals for these rates and p values for comparing the pharmacist and technician checkers were computed using SAS, version 6.12 (SAS Institute, Cary, NC). An additional analysis was conducted to ensure that wide variation in accuracy rates among individual technicians did not exist, since this could result in a favorable mean accuracy rate and mask the performance of one or more technicians who performed below the established goal of 99.8%. Mixed-effects logistic regression models with a random-checker effect were used to confirm the results.

Results

Twenty-nine pharmacists (15 at CSMC, 14 at LBMMC) participated in Phase I of the study to supply baseline data of the checking accuracy of pharmacists. A total of 41 technicians (24 at CSMC, 16 at LBMMC, and 1 working at both), three of whom were interns, participated in Phase II of the study. All 41 technicians successfully completed the didactic training, 39 successfully completed the audits and became certified checkers for Phase III, and 2 technicians (including 1 of the interns) did not complete the certification audits because they were reassigned or had resigned.

Table 1 lists the combined-institution accuracy rates of pharmacist and technician checkers in Phase I and II, respectively. For technicians, both the observed average accuracy rate and its lower confidence limit exceeded the minimum requirement of 99.8% for a certified checker. The difference in accuracy rates between pharmacists and technicians was significant ($p < 0.0001$). Interestingly, the mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The two pharmacy interns had accuracy rates of 99.89% and 99.97%. One technician had an accuracy rate of 99.75%, which was just below the target rate, and subsequently met the minimum requirement and became certified after the next audit.

In Phase III, all certified technicians at both institutions maintained a minimum accuracy of 99.8% during their monthly and quarterly audits. Phase III began in April 1999; through December 2001, no certified technician checker had failed any quality assurance audits. However, some technicians were removed from the list of certified checkers during the study period because of work reassignments or other non-study-related issues. The board of pharmacy was continually updated on the names of certified technician checkers in the semiannual reports submitted.

Discussion

The proposition of allowing trained technicians to check unit dose medication cassettes filled by other technicians has been hotly debated in California in the past decade (appendix). This study's results appear to support the ability of well-trained technicians to accurately check unit dose medications.

Several studies have been published evaluating the accuracy of pharmacy technicians in checking other technicians in a unit dose medication fill system.[7-13] Our results corroborate the findings from these studies; in fact, we observed a higher accuracy rate for technicians than for pharmacists ($p < 0.0001$). The boards of pharmacy in Kansas, Minnesota, and Washington currently allow technicians to check unit dose medication cassettes filled by other technicians. In addition, the American Society of Health-System Pharmacists and the

Table 1.
Accuracy of Pharmacists and Technicians in Checking Unit Dose Medication Cassettes

Checker	No. Participants	No. Doses Checked	Mean Accuracy Rate(%)[a]	95% Confidence Interval (%)
Pharmacists	29	35,829	99.52	99.44–99.58
Technicians[b]	39	161,740	99.89	99.87–99.90

[a]The difference in accuracy rates between pharmacists and technicians is significant ($p < 0.0001$), using mixed-effects logistic regression models.
[b]Includes two pharmacy interns who were employed and functioning as technicians.

California Society of Health-System Pharmacists (professional policy 9801, October 1998) support the role of the technician in checking unit dose medication cassettes.

The expansion of the technician's role has been shown to increase pharmacists' productivity.[14] We estimated that pharmacists at each institution spent approximately one hour per day per pharmacist checking unit dose medication cassettes before the program was implemented. In this experimental program, the pharmacists were able to use this additional time to expand clinical services and respond to drug therapy-related requests from physicians, such as dosing recommendations. The training and auditing of technicians for checking medication cassettes are centralized and carried out by the technician supervisor, who is under the direction of a pharmacist manager. By centralizing this responsibility, decentralized pharmacists gain additional time for direct patient care activities. Also, pharmacists at both institutions have reported an increase in job satisfaction after implementing the experimental program.

When evaluating the study results, some limitations should be acknowledged. The pharmacist checkers selected to determine the baseline accuracy rate of checking unit dose medication cassettes were those who happened to be staffing the inpatient areas on the dates that the audits were performed. Neither the pharmacist checkers nor the dates of the audits were randomized. The pharmacists and the technicians were cognizant of the study, although they did not necessarily know when audits were to be conducted. Artificial errors introduced were not randomized using a random numbers table but were based on the judgment of the pharmacist auditors who attempted to introduce a variety of different errors. The auditors at each institution introduced errors independently. In addition, the severity of errors was not defined in the study; therefore, this information was not included in the results.

The results of this study were presented to the California State Board of Pharmacy, which is now reconsidering allowing technicians to check unit dose cassettes filled by other technicians in the inpatient setting, under the same conditions of this study. The waiver for this study expires in December 2002. Until state regulations are changed or the expiration date is reached, both institutions will continue to gather data from the quarterly audits.

Conclusion

In this study, we concluded that pharmacy technicians who had been trained and certified in a closely supervised program that incorporates quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

References

1. Ernest FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost of illness model. *J Am Pharm Assoc.* 2001; 41:192-9.
2. Leape LL, Cullen DJ, Clapp MD et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999; 282: 267-70.
3. Agency for Healthcare Research and Quality. Making healthcare safer: a critical analysis of patient safety practices; the clinical pharmacist's role in preventing adverse drug events. www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf (accessed 2001 Aug 4).
4. Rudis MI, Brandl KM. Position paper on critical care pharmacy services. *Crit Care Med.* 2000; 28:3746-50.
5. U.S. Department of Health and Human Services. The pharmacist workforce: a study of the supply and demand for pharmacists. Report to Congress. http://bhpr.hrsa.gov/healthworkforce/pharmacist.html (accessed 2001 Aug 2).
6. Advisory Board daily briefing. Pharmacist shortage may increase risk of medication errors. www.dailybriefing@advisory.com (accessed 2001 Aug 27).
7. Woller TW, Stuart J, Vrabel R et al. Checking of unit dose cassettes by pharmacy technicians at three Minnesota hospitals. *Am J Hosp Pharm.* 1991; 48:1952-6.
8. Lovett LT, Spangler LC. System for checking the accuracy of filled unit dose cassettes by pharmacy technicians. Paper presented at ASHP Midyear Clinical Meeting. San Francisco, CA; 1980 Dec 11.
9. Grogan JE, Hanna JA, Haight RA. A study of accuracy of pharmacy technicians working in a unit dose system. *Hosp Pharm.* 1978; 13:194-9.
10. Ness JE, Sullivan SD, Stergachies A. Accuracy of technicians and pharmacists in identifying dispensing errors. *Am J Hosp Pharm.* 1994; 51:354-7.
11. Spooner SH, Emerson PK. Using hospital pharmacy technicians to check unit dose carts. *Hosp Pharm.* 1994; 29:433-4,436-7.
12. Becker MD, Johnson MH, Longe RL. Errors remaining in unit dose carts after checking by pharmacists versus pharmacy technicians. *Am J Hosp Pharm.* 1978; 35:432-4.
13. Gray SL, Parker PE. A Kansas hospital's certification of technician checking technician in unit dose cart-fill. *J Kans Pharm.* 1994; 68:8. Abstract.
14. Kalman MK, Witkowski DE, Ogawa GS. Increasing pharmacy productivity by expanding the role of pharmacy technicians. *Am J Hosp Pharm.* 1992; 49:84-9.

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians

Year	State Regulation
Before 1993	Acute care hospitals in California were permitted to allow technicians to check the accuracy of technician-filled inpatient unit dose medication cassettes, under chart order exemption in the pharmacy regulations.
1993	The use of inpatient pharmacy technicians to check technicians filling unit dose cassettes was deemed unacceptable by the California State Board of Pharmacy, as evidenced by the following correspondence provided to the California Association of Hospital and Health Systems: "Please note the law does not authorize a technician to check another technician. While a technician may check another technician, the final check must always be done by a pharmacist."

Continued on next page

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians *(continued)*

Year	State Regulation
1994	The Hospital Pharmacy Committee of the California State Board of Pharmacy proposed draft language to add a section to the California Code of Regulation (CCR1717) to allow pharmacy technicians to check the work of other pharmacy technicians in connection with filling unit dose medication cassettes for patients whose orders had been previously reviewed by a pharmacist.
1995	This draft language was presented in May at a board of pharmacy informational hearing.
1996	In June, as a result of failure to reach agreement over the proposed language, the board developed a technician committee. This committee was charged to evaluate the entire pharmacy technician program including changes necessary to improve the program, discuss and plan for future changes and roles of technicians, and pursue any statute or regulatory changes necessary to accommodate these practices.
	The committee, in an October report to the board, recommended several potential changes including asking the board to consider allowing technicians to check the work of other technicians for unit dose medication cassette filling under a waiver system that included specific provisions (e.g., functions). In response to this report, the board of pharmacy voted to move forward with regulatory action to allow technicians to check the accuracy of technicians' work in a unit dose medication cassette fill system. During this time, the board of pharmacy began to enforce the California Code of Regulations relating to the use of technicians for checking of unit dose medication cassettes and required facilities to discontinue the practice.
1997	In May, responding to requests from multiple health systems and the California Society of Health-System Pharmacists, the board of pharmacy gave notice of its intent to amend regulations to allow technician checking of technician-filled unit dose medication cassettes.
	All interested parties were provided an opportunity to provide oral testimony at the proposal hearing in July. At that time, the board of pharmacy did not approve moving forward with the amended regulations. In response to the many delays in reaching consensus to change current regulations, representatives from LBMMC and CSMC developed the proposal in collaboration with the University of California, San Francisco, School of Pharmacy to perform a study in order to provide the board with objective data.
1998	On May 27, the board granted the requested waiver of the California Code of Regulations to conduct the "experimental program." The waiver was initially granted until November 1, 2000. However, the waiver was subsequently extended until February 1, 2001.
2001	In January, having reviewed the results of this study, the board extended the waiver until December 2002.

White Paper on Pharmacy Technicians 2002: Needed Changes Can No Longer Wait

Introduction

The counting and pouring now often alleged to be the pharmacist's Chief occupation will in time be done by technicians and eventually by automation. The pharmacist of tomorrow will function by reason of what he knows, increasing the efficiency and safety of drug therapy and working as a specialist in his own right. It is in this direction that pharmaceutical education must evolve without delay.

—Linwood F. Tice, D.Sc.,
Dean, Philadelphia College of
Pharmacy and Science (1966)[1]

Health care and the profession of pharmacy have changed enormously since Dr. Tice articulated this vision more than 35 years ago. The role of the pharmacy technician has like-wise undergone substantial change. Technicians have increased in number. They may access a wide array of training opportunities, some of which are formal academic programs that have earned national accreditation. Technicians may now seek voluntary national certification as a means to demonstrate their knowledge and skills. State boards of pharmacy are increasingly recognizing technicians in their pharmacy practice acts.

Nonetheless, Dr. Tice' vision remains unrealized. Although pharmacy technicians are employed in all pharmacy practice settings, their qualifications, knowledge, and responsibilities are markedly diverse. Their scope of practice has not been sufficiently examined. Basic competencies have not been articulated. Standards for technician training programs are not widely adopted. Board regulations governing technicians vary substantially from state to state.

Is there a way to bring greater uniformity in technician competencies, education, training, and regulation while ensuring that the technician work force remains sufficiently diverse to meet the needs and expectations of a broad range of practice settings? This is the question that continues to face the profession of pharmacy today as it seeks to fulfill its mission to help people make the best use of medications.

The purpose of this paper is to set forth the issues that must be resolved to promote the development of a strong and competent pharmacy technician work force. Helping pharmacists to fulfill their potential as providers of pharmaceutical care would be one of many positive outcomes of such a development. The paper begins with a description of the evolution of the role of pharmacy technicians and of their status in the work force today. The next section sets forth a rationale for building a strong pharmacy technician work force. The paper then turns to three issues that are key to realizing the pharmacy technician' potential: (1) education and training, (2) accreditation of training institutions and programs, and (3) certification. Issues relating to state regulation of pharmacy technicians are then discussed. The paper concludes with a call to action and a summary of major issues to be resolved.

Many of the issues discussed in this report were originally detailed in a white paper developed by the American Pharmaceutical Association (APhA) and the American Society of Health-System Pharmacists (ASHP), which was published in 1996.[2] For this reason, this paper focuses primarily on events that have occurred since that time. Other sources used in the preparation of this paper include Institute of Medicine (IOM) reports,[3,4] report to the U.S. Congress on the pharmacy work force,[5] and input from professional associations representing pharmacists and technicians as well as from educators, regulators, and consumers.

The Pharmacy Technician: Past to Present

A pharmacy technician is "an individual working in a pharmacy [setting] who, under the supervision of a licensed pharmacist, assists in pharmacy activities that do not require the professional judgment of a pharmacist."[6] The technician is part of a larger category of "supportive personnel," a term used to describe all non-pharmacist pharmacy personnel.[7]

There have been a number of positive developments affecting pharmacy technicians in the past decade, including national certification, the development of a model curriculum for pharmacy technician training, and greater recognition of pharmacy technicians in state pharmacy practice acts. The role of the pharmacy technician has become increasingly well defined in both hospital and community settings. Technicians have gained greater acceptance from pharmacists, and their numbers and responsibilities are expanding.[8-11] They are starting to play a role in the governance of state pharmacy associations and state boards of pharmacy. Yet more needs to be done. There is still marked diversity in the requirements for entry into the pharmacy technician work force, in the way in which technicians are educated and trained, in the knowledge and skills they bring to the workplace, and in the titles they hold and the functions they perform.[12,13] absence of uniform national training standards further complicates the picture. Because of factors such as these, pharmacists and other health professionals, as well as the public at large, have varying degrees of understanding and acceptance of pharmacy technicians and their role in health care delivery.

An awareness of developments relevant to pharmacy technical personnel over the last several decades is essential to any discussion of issues related to current and future pharmacy technicians.[14,15] Policy statements of a number of national pharmacy associations are listed in the appendix. A summary of key events of the past half century follows.

1950s–1990s. Beginning in the late 1950s, hospital pharmacy and ASHP took the lead in advocating the use of pharmacy technicians (although the term "pharmacy technician" had not yet come into use), in developing technician training programs, and in calling for changes needed to ensure that the role of technicians was appropriately articulated in state laws and regulations.[16] Among the initial objectives was to make a distinction between tasks to be performed by professional and nonprofessional staff in hospital and community settings. This was largely accomplished by 1969.[14,17]

In the community pharmacy sector, chain pharmacies supported the use of pharmacy technicians and favored on-the-job training. By contrast, the National Association of Retail Druggists (NARD, now the National Community Pharmacist Association [NCPA]), in 1974, stated its opposition to the use of technicians and other "subprofessionals of limited training" out of concern for public safety.[14]

Largely because of its origins, technician practice was initially better defined and standardized in hospitals than in community pharmacies. As the need for technicians in both settings became increasingly apparent, however, many pharmacists and pharmacy educators began to call for collaborative discussions and greater standardization on a number of issues related to pharmacy technicians, and in recent years, progress has been made toward this goal.

The Pharmacy Technician Work Force Today. Based on Pharmacy Technician Certification Board (PTCB) and Bureau of Labor Statistics (BLS) estimates, there are as many as 250,000 pharmacy technicians in the United States.[8,18] This is a significant increase over the 1996 estimate of 150,000.[2] BLS predicts that pharmacy technician employment will grow by 36% or more between 2000 and 2010.[8] This percentage of growth is "much faster than the average for all occupations," but in line with a majority of other supportive personnel in the health care sector.

Pharmacy technicians work in a wide variety of settings, including community pharmacies (approximately 70% of the total work force), hospitals and health systems (approximately 20%), long-term-care facilities, home health care agencies, clinic pharmacies, mail-order pharmacies, pharmaceutical wholesalers, managed care organizations, health insurance companies, and medical computer software companies.[8] The 2001 Schering Report found that 9 out of 10 community pharmacies employ pharmacy technicians.[10] Recent studies conducted in acute care settings indicate that this figure is nearly 100% for the hospital sector.[19]

What functions do technicians perform? Their primary function today, as in decades past, is to assist with the dispensing of prescriptions. A 1999 National Association of Chain Drug Stores (NACDS)/Arthur Andersen study revealed that, in a chain-pharmacy setting, pharmacy technicians' time was spent on dispensing (76%), pharmacy administration (3%), inventory management (11%), disease management (<1%), and miscellaneous activities, including insurance-related inquiries (10%).[21] Surveys conducted by PTCB have yielded similar results.[18,21] The nature of dispensing activities may be different in a hospital than in a community pharmacy. In hospitals, technicians may perform additional specialized tasks, such as preparing total parenteral nutrition solutions, intravenous admixtures, and medications used in clinical investigations and participating in nursing-unit inspections.[22]

In the past, pharmacists have traditionally been reluctant to delegate even their more routine work to technicians.[14] The 2001 Schering Report concluded that, in the past five years, pharmacists have become more receptive to pharmacy technicians. Indeed, much has changed in the scope of potential practice activities for pharmacy technicians and pharmacy's perception of the significant role technicians might play.[10,22] New roles for pharmacy technicians continue to emerge as a result of practice innovation and new technologies.[9,11] Despite their expanded responsibilities, many technicians believe that they can do more. For example, one study reported that 85% of technicians employed in chain pharmacies, compared with 58% of those working in independent pharmacies, felt that their knowledge and skills were being used to the maximum extent.[10]

Pharmacy Technicians: The Rationale

Several developments in health care as a whole, and in pharmacy in particular, have combined to create an increasing demand for pharmacy technicians. Three of significant importance are the pharmacist work force shortage, the momentum for pharmaceutical care, and increased concern about safe medication use.

Pharmacist Work Force Shortage. In 1995, a report by the Pew Health Professions Commission predicted that automation and centralization of services would reduce the need for pharmacists and that the supply of these professionals would soon exceed demand.[23] The predicted oversupply has failed to materialize; in fact, there is now a national shortage of pharmacists. A 2000 report of the federal Health Resources and Services Administration (HRSA) stated, "While the overall supply of pharmacists has increased in the past decade, there has been an unprecedented demand for pharmacists and pharmaceutical care services, which has not been met by the currently available supply."[5] The work force shortage is affecting all pharmacy sectors. Ongoing studies (by the Pharmacy Manpower Project and others) indicate that the pharmacy personnel shortages will not be solved in the short term.[24]

For pharmacy practitioners, the results of the work force shortage are clear: more work must be done with fewer pharmacist staff. Between 1990 and 1999, the number of prescriptions dispensed in ambulatory care settings increased by 44%, while the number of active pharmacists per 100,000 people increased by only about 5%.[5] Chain pharmacists now fill an average of 86 prescriptions during a normal shift—a 54% increase since 1993.[25] NACDS and IMS HEALTH estimate that, between 1999 and 2004, the number of prescriptions will increase by 36% while the number of pharmacists will increase by only 4.5% (Figure 1).[26]

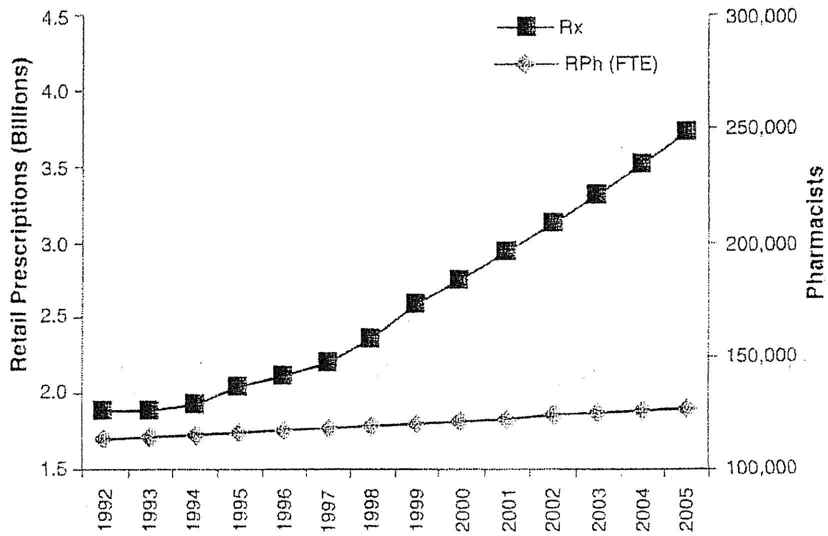
Faced with greater numbers of prescriptions to dispense, pharmacists have less time to counsel patients. Working conditions and schedules have deteriorated, and job-related stress has risen.[10] Professional satisfaction has diminished. Perhaps most ominous, fatigue and overwork increase the potential for medication errors.[5,27]

Increased use of technicians is one obvious way of reducing workload pressures and freeing pharmacists to spend more time with patients. A white paper issued in 1999 by APhA, NACDS, and NCPA emphasized the need for augmenting the pharmacist's resources through the appropriate use of pharmacy technicians and the enhanced use of technology.[28]

The situation in pharmacy is not unique. A report from the IOM concluded that the health care system, as currently structured, does not make the best use of its resources.[4] Broader use of pharmacy technicians, in itself, will not solve the pharmacist work force crisis. It would ensure, however, that the profession makes better use of existing resources.

Momentum for Pharmaceutical Care. More than a decade ago, Hepler and Strand[29] expressed the societal need for pharmaceutical care. Since that time, the concept has been refined, and its impact on the health care system and patient care has been documented. Studies have shown that pharmaceutical care can improve patient outcomes, reduce the

Figure 1. Community prescriptions and pharmacists, 1992–2005. Rx = prescriptions, RPh (FTE) = registered pharmacist (full-time equivalent). Reprinted, with permission, from reference 26.



incidence of negative therapeutic outcomes, and avoid the economic costs resulting from such negative outcomes.[30-33] Nonetheless, other studies indicate that pharmacists continue to spend much of their time performing routine product-handling functions.[19,20] Widespread implementation of pharmaceutical care, a goal for the entire profession, has been difficult to achieve thus far.

Technicians are instrumental to the advancement of pharmaceutical care. As Strand[34,35] suggested, prerequisites to successful implementation of pharmaceutical care include enthusiastic pharmacists, pharmacy supportive personnel willing to work in a pharmacy where dispensing is done by technicians rather than pharmacists, and a different mindset i.e., the pharmacist will no longer be expected to "count and pour" but to care for patients.

In other words, implementation of pharmaceutical care requires a fundamental change in the way pharmacies operate. Pharmacists must relinquish routine product-handling functions to competent technicians and technology. This is a difficult shift for many pharmacists to make, and pharmacists may need guidance on how to do it. For example, they may need training in how to work effectively with technicians. Recognizing this need, some practice sites have developed successful practice models of pharmacy technicians working with pharmacists to improve patient care. Several of these sites have been recognized through PTCB's "Innovations in Pharmaceutical Care Award."[36]

Safe Medication Use. Used inappropriately, medications may cause unnecessary suffering, increased health care expenditures, patient harm, or even death.[33] Ernst and Grizzle[37] estimated that the total cost of drug-related morbidity and mortality in the ambulatory care setting in 2000 was more than $177 billion—more than the cost of the medications themselves. They stressed the urgent need for strategies to prevent drug-related morbidity and mortality.

The problems associated with inappropriate medication use have received broad publicity in recent years. For example, *To Err Is Human: Building a Safer Health System* drew attention to medical errors.[3] It criticized the silence that too often surrounds the issue. Many members of the public were shocked to realize that the system in which they place so much trust was far from perfect.

Sometimes pharmacists have been implicated in medication errors. Technicians, too, have not escaped culpability.[38-43] Several studies, most of which were performed in hospitals, have, however, demonstrated that appropriately trained and supervised pharmacy technicians can have a positive effect on equalizing the distributive workload, reducing medication errors, allowing more time for clinical pharmacy practice, and checking the work of other technical personnel.[44,45] One study found that pharmacy technicians, when specially trained for the purpose, were as accurate as pharmacists in checking for dispensing errors.[46] The United States Pharmacopeia Medication Errors Reporting Program (USPMERP) has noted the contributions that pharmacy technicians can make to medication error prevention through their involvement in inventory management (e.g., identifying problems relating to "look-alike" labeling and packaging).[47] USPMERP also affirms that a "team approach" and "proactive attitudes" of pharmacists and technicians are important elements in reducing medication errors. The National Coordinating Council for Medication Error Reporting and Prevention advocates that a series of checks be established to assess the accuracy of the dispensing process and that, whenever possible, an independent check by a second individual (not necessarily a pharmacist) should be made.[48]

Reports such as these call for an expanded role for pharmacy technicians in a much-needed, systematic approach to medication error prevention.

Preparing Pharmacy Technicians for Practice

Historical Overview. Originally, all pharmacy technicians received informal, on-the-job training. The majority of pharmacy technicians are probably still trained this way.[8,18,49,50] Nevertheless, formal training programs, some of which are provided at the work site, are becoming more widespread. As state regulations, medications, record-keeping, and insurance requirements have become more complex, there has been a move toward more formal programs.[51] Some employers have found that formal training improves staff retention and job satisfaction.[18,52] Another advantage of a formal training program is that it can confer a sense of vocational identity.[49]

Formal training programs for pharmacy technicians are not new; they were introduced in the armed forces in the early 1940s, and more structured programs were developed by the military in 1958. In the late 1960s, the Department of Health, Education, and Welfare recommended the development of "pharmacist aide" curricula in junior colleges and other educational institutions.[14] The first formal hospital-based technician training program was initiated around this time. Training programs proliferated in the 1970s as the profession sought to meet the need for a differentiated pharmacy work force.[53] Many of these programs were established in response to requests from hospital pharmacy administrators; at that time there was little interest in formally trained technicians in community pharmacies who continued to train technicians on the job.[54]

In the 1980s, ASHP issued training guidelines intended to help hospital pharmacists develop their own training programs.[7] ASHP recommended minimum entry requirements for trainees and a competency evaluation that included written, oral, and practical components. The guidelines were used not only by hospitals but by vocational schools and community colleges that wanted to develop certificate and associate degree programs.[49]

Acknowledging the importance of a common body of core knowledge and skills for all pharmacy technicians that would complement site-specific training, NACDS and NCPA developed a training manual, arranged into nine instructional sections and a reference section.[55] Each section has learning objectives, self-assessment questions, and competency assessment for the supervising pharmacist to complete. The manual focuses on the practical, legal, and procedural aspects of dispensing prescriptions, sterile-product compounding, patient interaction, and reimbursement systems. APhA and ASHP also produce technician training manuals and resource materials for pharmacy technicians.[56-60]

To date, most programs have referred to the "training" rather than the "education" of pharmacy technicians. Further discussion of the need for clarification of the education and training needs of pharmacy technicians is provided below.

Academic Training Programs. In 2002, approximately 247 schools and training institutions in 42 states offered a range of credentials, including associate degrees, diplomas, and certificates, to pharmacy technicians. The military also continues to provide formal training programs for pharmacy technicians.

Formal technician training programs differ in many respects, one of which is length. The *Accrediting Commission of Career Schools and Colleges of Technology School Directory* lists 36 "pharmacy" programs.[12] These programs vary in length from 540 to 2145 contact hours (24–87 weeks), with a median of 970 hours. ASHP, which accredits technician training programs, requires that programs have a minimum of 600 contact hours and a minimum duration of 15 weeks.[61] The Pharmacy Technicians Educators Council (PTEC), an association representing pharmacy technician educators, supports the ASHP minimum requirements.[62]

The minimum acceptable length of the program is a matter of debate. Some pharmacy technician educators deplore a move within the education system to get people into the work force quickly. They believe that the pharmacy profession should make it clear that, while work force shortages and the needs of the marketplace are important considerations, rapid-training strategies do not seem appropriate for health care personnel whose activities directly affect the safe and effective use of medications.[51] There should be a clear relationship between the nature and intensity of education, training, and the scope of practice.

Entrance requirements for training programs also vary. Some have expressed concern that a substantial number of trainees may lack the necessary basic skills and aptitude to perform the functions expected of technicians.[51] The fact that about 30% of a certified pharmacy technician's time is spent performing tasks that require mathematical calculations reinforces the importance of suitably qualified training applicants.[21] ASHP acknowledged the need for minimum qualifications for training program applicants more than 20 years ago, but the issue continues to be a matter of debate.[7]

Progress Toward Standardization: The Model Curriculum. The absence of national training standards and the resultant variations in program content, length, and quality are barriers to the development of a strong technician work force. The problem is not unique to pharmacy technician training; other occupations in the health care sector also lack national standards. Nonetheless, it is ironic that persons in certain other occupations whose services have far less impact on public safety than do those of pharmacy technicians (e.g., barbers and cosmetologists) have training programs that, on average, are longer and less diverse than are pharmacy technician programs.[63] Reflecting a common sentiment on this issue, a 1999 PTEC survey concluded that "Expansion of the role of pharmacy technicians must be in tandem with standardizing training and establishment of competencies. Increased responsibilities should be commensurate with increased education."[64] Likewise, there was a consensus at the Third PTCB Stakeholders' Forum, held in June 2001, that national standards for pharmacy technician training are needed.[65]

Progress toward standardization has been facilitated by the *Model Curriculum for Pharmacy Technician Training*.[66] Having taken the initiative and the leadership role, ASHP collaborated with several other pharmacy associations (APhA, the American Association of Pharmacy Technicians, PTEC, the American Association of Colleges of Pharmacy [first edition only], and NACDS [second edition only]) to develop the *Model Curriculum*. The first edition, released in 1996, was based on the findings of the 1992–94 *Scope of Pharmacy Practice Project*.[67] Many of the revisions in the second edition, released in 2001, were based on a 1999 PTCB task analysis and accounted for changes in the scope of activities of today's pharmacy technicians as well as changes expected to occur over the next five years.[21,22] Significant changes were made, for example, in sections dealing with the technician's role in enhancing safe medication use, assisting with immunizations, and using "tech–check–tech" (a system in which pharmacy technicians are responsible for checking the work of other technicians with minimal pharmacist oversight).

The organizations that developed the model curriculum do not expect that every training program will cover every goal and objective of the curriculum; rather, the curriculum should be seen as a "menu" of possible learning outcomes. The model curriculum provides a starting point for identifying core competencies for pharmacy technicians.[22] It acknowledges the need for a level of understanding of basic therapeutics, anatomy, physiology, and pharmacology. The curriculum does not include recommendations regarding the relative amount of time that should be allotted to each module, but such guidelines are under consideration.[68]

The Future Preparation of Pharmacy Technicians: Education Versus Training. Virtually all the consensus-development meetings and studies that have investigated training requirements for pharmacy technicians have called for the development of standardized training in some form.[51,69] APhA and ASHP concur with this position.[2,70,71]

Such a recommendation would best be accompanied by two important caveats. The first is that any national standards for education and training of pharmacy technicians will not eliminate the need for additional, site-specific training that focuses on local policies and procedures.[52,65] Second, standards-based education or training can conceivably be delivered successfully in a variety of different settings.

However, what exactly is meant when the terms education and training are applied to pharmacy technicians? They have tended in the past to be used somewhat interchangeably. However, a distinction needs to be made and a balance between the two needs to be reached to ensure that pharmacy technicians are adequately and appropriately prepared to perform, in a safe and efficient manner, the functions and responsibilities that are assigned to them—both now and in the future. As has already been noted in this paper, the roles and responsibilities of pharmacy technicians have evolved and expanded in recent years. While, in the main, pharmacy technicians perform routine tasks that do not require the professional judgment of a pharmacist, state pharmacy practice acts now recognize that pharmacy technicians are being assigned new and different functions in the practice setting, some of which may require a higher level of judgment or extensive product knowledge and understanding.

Training involves learning through specialized instruction, repetition and practice of a task or series of tasks until proficiency is achieved. Education, on the other hand, involves a deeper understanding of a subject, based on explanation and reasoning, through systematic instruction and teaching. People may be proficient in performing a task without knowing why they are doing it, why it is important, or the logic behind the steps being performed. While education (as described above) may involve a training component, both are vital to the learning (or preparation) of the technician. Barrow and Milburn[72] give a useful treatise on this subject. The education and training of pharmacy technicians and other supportive personnel must be commensurate with the roles they are performing. To ensure quality, both the education and training components should be standards based.

Accreditation of Pharmacy Technician Education and Training

The Council on Credentialing in Pharmacy (CCP) defines accreditation as "the process by which a private association, organization, or government agency, after initial and periodic evaluations, grants recognition to an organization that has met certain established criteria."[73] Accreditation is an integral aspect of ensuring a quality educational experience.

For pharmacy technician education and training, there are two types of accreditation: programmatic (also referred to as specialized) and institutional. Programmatic accreditation focuses specifically on an individual program, whereas institutional accreditation evaluates the educational institution as a whole, with less specific attention paid to the standards of individual programs offered by the institution. Institutional accreditors operate either on a regional or national basis; the latter usually has a more focused area of interest. A system of dual accreditation, in which institutional accreditation is conducted by regional accrediting bodies and programmatic accreditation is conducted by the American Council on Pharmaceutical Education (ACPE), has worked well for schools and colleges of pharmacy since the 1930s.

Based on information obtained from published directories, it is estimated that only 43% of the 247 schools and training institutions referred to earlier are accredited by bodies specializing in technical, allied health, and paraprofessional education; 36% have their programs accredited by ASHP; and 12% are accredited by both ASHP and one or more of the institutional accrediting bodies specializing in technical, allied health, and paraprofessional education.

Institutional Accreditation. For institutions offering pharmacy technician training, national institutional accreditation is carried out by at least four agencies: the Accrediting Commission of Career Schools and Colleges of Technology (ACCSCT), the Accrediting Bureau of Health Education Schools (ABHES), the Council on Occupational Education (COE), and the Accrediting Council for Independent Colleges and Schools (ACICS). All of these agencies are recognized by the U.S. Department of Education. None has a formal national affiliation with the profession of pharmacy.

Because there are no nationally adopted standards for pharmacy technician training, it is difficult for institutional accrediting bodies to set detailed program requirements. ACCSCT standards require programs to have an advisory committee, the majority of whose members represent employers in the field of training.[74] ABHES has a suggested curriculum outline for pharmacy technician programs. In an effort to improve the quality of their programs, COE and ABHES plan to switch from institutional to program accreditation.[75] Of some concern is the fact that such accreditation systems (for pharmacy technician training programs) would be outside the pharmacy profession and would not be based on national standards recognized by the profession.

Program Accreditation. Program accreditation for technician training is offered by ASHP. ASHP accreditation of technician training programs began in 1982 at the request of hospital pharmacists. Many hospital-based technician training programs were already using ASHP's guidelines and standards, but they expressed a need for a more formal method of oversight to ensure the quality of training. ASHP had already accredited pharmacy residency programs and moving into technician accreditation seemed a logical step.

Initially, nearly all ASHP-accredited programs were hospital based. This is no longer the case; of the 90 technician training programs currently accredited by ASHP, only 3 are hospital based. Over 90% of programs are located at vocational, technical, or community colleges.[76]

The objectives, standards, and regulations of the accreditation program, as well as a directory of accredited programs, are available on the ASHP Web site.[61,76-78] The accreditation standards are geared toward preparing technicians for all practice settings and require that pharmacy technicians be trained in a wide variety of practice environments and complete laboratory exercises before beginning their experiential training.

While accreditation is voluntary for both pharmacy degree programs and technician training programs, an important distinction exists. State boards of pharmacy and the National Association of Boards of Pharmacy (NABP) have recognized ACPE accreditation as an eligibility requirement for the North American Pharmacy Licensure Examination (NAPLEX).[79] Completion of an accredited program is not usually a prerequisite for employment, registration, or certification as a pharmacy technician. However, accreditation does bring a number of benefits. For the program, the benefits include enhanced recruitment potential for trainees, improved marketing, and the opportunity for peer review and quality improvement. For employers, completion of an accredited program may be an indication of the level of competence of a technician. Most importantly, accreditation provides all stakeholders with an objective, external, and independent evaluation of the quality of the education or training experience. Employers have a strong interest in the quality of training of their employees, not least of which is in terms of potential liability issues if the employer provides the training. Therefore, it would appear to be in the best interest of employers for the onus of quality assurance to rest with an independent party.

A New Role for ACPE? ASHP recognizes that the education, training, and utilization of pharmacy technicians now have broader professional implications than when it introduced its accreditation program began in 1982. For this reason, ASHP has asked ACPE to explore assuming responsibility for this function. Many people now believe that accreditation is best left to an independent agency that has no direct or indirect interest in the provision of training or in the activities of the graduates of the training program.[80]

Involving ACPE might have an additional advantage, should a decision be made to develop national training standards. ACPE, which has broad experience spearheading collaborative efforts to develop educational standards for pharmaceutical education, could be an appropriate organization to lead the process of developing uniform national standards for technician education and training. Responses to a 2000 ACPE survey indicate that more than 80% of respondents support further exploration of an ACPE role in this area.

Certification of Pharmacy Technicians

Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.[2] For pharmacy, the PTCB, created in 1995, has been one of the most positive developments of the past decade.

"Certified pharmacy technician" (CPhT) is the only national credential available to pharmacy technicians. A credential is documented evidence of an individual's or program's qualifications or characteristics. Credentials may include diplomas, licenses, certificates, and certifications.[73] CCP was established in 1999. The development and application of credentialing standards for the pharmacy profession are integral components of CCP's vision and mission statements. PTCB was one of CCP's founding organizations. For a pharmacy technician, certification is an indication of the mastery of a specific core of knowledge.[2] Certification is mainly voluntary, although some state boards of pharmacy now require certification of technicians.

The PTCB examination is based on a task analysis that defined the work of pharmacy technicians nationwide: 64% of the exam is based on knowledge required to assist the pharmacist in serving patients, 25% on medication distribution and inventory control systems, and 11% on the administration and management of pharmacy practice.[21] By the end of 2001, more than 100,000 technicians had been certified with this program.[37] CPhTs must renew their certification every two years and complete at least 20 hours of pharmacy-related continuing education (including 1 hour of pharmacy law) during that period of time.

For many technicians, achieving PTCB certification is an important part of their professional development.[18] Many pharmacy chains have recognized the value of certification and provide assistance and incentives to staff to achieve certification, including reimbursement of costs, advancement to a higher grade, and a salary increase.[18] Studies have revealed that certified technicians remain in practice longer than do noncertified technicians.[81,82] Staff turnover, including both pharmacists and technicians, has decreased in pharmacies that employ certified technicians. Improved staff morale, higher productivity, reduced errors, and higher levels of customer satisfaction have also been noted. Additional benefits for employers include improved risk management, reduced technician training times, and lower training costs.[84] Some pharmacists feel more confident delegating dispensing activities to certified technicians than to technicians who are not certified.[10,21]

PTCB recognizes the need to reassess and modify its policies and procedures, as well as the examination, in response to the changing needs of pharmacy practice, the profession, and trends in the marketplace. To make such assessments, PTCB conducts research and seeks input from its stakeholders. PTCB also reviews its eligibility criteria for candidates who wish to sit for the certification examination. Under consideration are specialty certification assessments in areas such as preparation of intravenous admixtures and third-party-payment systems.

Regulation of Pharmacy Technicians

For many years, most state boards of pharmacy, often reflecting the attitudes of pharmacists, opposed recognizing technicians and expanding the scope of their activities.[52,14] As pharmacists' roles changed and use of supportive personnel expanded, these attitudes began to shift. Over the past five years, a majority of states have revised their pharmacy practice acts in areas related to technicians. Today, Ohio is the only state that does not formally address pharmacy technicians in state statutes or regulations.

NABP regularly surveys state pharmacy practice acts. The results of these surveys are bellwethers of change at the state level; collectively, they reveal trends. The most recent survey was conducted in 2001.[13] To highlight changes that have taken place since the publication of the 1996 "White Paper on Pharmacy Technicians,"[2] the results of NABP's 1996–1997[84] and 2001–2002[13] surveys were compared. NABP also appoints task forces to study and make recommendations on major issues. The deliberations of these task forces have resulted in, among other things, a call for formal recognition of pharmacy technicians, simplified state registration procedures, site-specific training, a national technician competency examination, and a disciplinary clearinghouse. Key developments in regulation, as evidenced in the NABP surveys and in recent NABP task force recommendations and actions, are summarized below.

Changes in State Regulations: 1996–2001. *Terminology.* In the 1996–1997 NABP survey, at least 11 terms were used to describe pharmacy supportive personnel. At that time, 24 states used the term "pharmacy technician." By 2001, 38 states had adopted this designation.

Technician Registration. In its "model act," designed to provide boards of pharmacy with model language that can be used when developing state laws or board rules, NABP advocates that pharmacists be licensed and that pharmacy technicians be registered.[85] "Registration" is defined as the process of making a list or being included on a list. It carries no indication or guarantee of the registrant's knowledge or skills. "Licensure" is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected.[2] Like NABP, ASHP and APhA support registration and oppose licensure of pharmacy technicians. APhA and ASHP believe that licensed pharmacists must retain responsibility and accountability for the quality of service in a pharmacy.[72,73,86]

By 2001, 24 states required registration and 5 required licensure of pharmacy technicians, in accordance with NABP's recommendations. Although the term "license" is used in these regulations, in some cases the process would appear to more closely resemble "registration" in terms of the definitions used in this paper. The increase in the number of states (up from 14 in 1996) that now require either registration or licensure of pharmacy technicians is noteworthy.

Pharmacist-to-Technician Ratios. Since 1996, at least 25 states have liberalized their pharmacist-to-technician ratios (from a norm of 1:1 or 1:2 to 1:2 or 1:3). Some states further relaxed ratios in sites where certified pharmacy technicians are employed. In their 1996 white paper, APhA and ASHP called for a reassessment of mandated arbitrary pharmacist-to-technician ratios.[2] This stance reflects the organizations' conviction that pharmacists should be responsible and accountable for pharmacy technicians under their charge.[70,71] NACDS believes that each practice setting should be allowed to determine its own optimal ratio. Following the recommendation of a 1999 Task Force on Standardization of Technicians' Roles and Competencies,[88] NABP encouraged states to modify or eliminate ratios in pharmacy settings with quality assurance programs in place.

Standard Training Requirements. Between 1996 and 2001, the number of states that had incorporated training requirements into their regulations rose by 34% (from 19 to 26). Training requirements had been recommended in 1996 by an NABP task force.

The training requirements that state boards have put in place are, in some cases, minimal. Many states require nothing more than a training manual; there are no detailed minimum requirements. California, Kansas, Indiana, and Washington, on the other hand, have enacted competency-based regulations or well-defined standards for training program assessment. Some states require continuing education for renewal of registration or licensure; others are considering such a requirement.

Technician Certification. Louisiana, New Mexico, Texas, Utah, Virginia, and Wyoming have made certification a requirement for registration or licensure. Texas was the first to introduce the requirement in 1996. The law was implemented in January 2001; a provision exists, however, for certain technicians to be exempted.[89] In Utah, the licensing authority has defined compliance with minimum training standards, as well as certification and the passing of a law examination, as requirements for licensure.[90] Alaska, Arizona, Kentucky, Massachusetts, Minnesota, North Carolina, Oregon, Tennessee, and Texas have altered pharmacist-to-technician ratios, responsibilities, supervision, or other requirements on the basis of a technician's certification status.

Levels of Personnel and Scope of Practice. Based on findings of its 1999 task force, NABP has recognized two levels of supportive personnel: pharmacy technician and certified pharmacy technician, and specified the scope of practice that would be allowed for technicians working under the supervision of a pharmacist.[91] Activities that cannot be performed by a pharmacy technician include drug-utilization review, clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification, patient counseling, dispensing-process validation, prescription transfer, and compounding. The following activities cannot be performed by a certified pharmacy technician: drug-utilization review, clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification, patient counseling, dispensing-process validation, and receipt of new prescription drug order when communicating by telephone or electronically unless the original information is recorded so the pharmacist can review the order as transmitted. The task force had recommended a third, and higher, level of supportive personnel—the pharmacist assistant—but NABP did not adopt this recommendation. APhA and ASHP likewise oppose the creation of this category of supportive personnel.[70,71]

Many of the changes in state regulations are reflected in the functions that technicians perform. For example, the number of states allowing a pharmacy technician to call a physician for refill authorization increased by 41% (from 25 to 36) in hospital and institutional settings and by 47% (from 24 to 36) in a community setting between 1996 and 2001. Few states have traditionally allowed pharmacy technicians in any work setting to accept called-in (new) prescriptions from a physician's office, and there was little change in this area over the past five years. There was also little change in the dispensing-related activities that pharmacy technicians perform; however, the percentage of states allowing these activities was already high (>85% in 1996). The only dispensing-related activity to show a more than 15% increase (in the number of states that allow it) in the past five years is the reconstitution of oral liquids, which increased by 22% (from 41 to 51) in hospitals and by 23% (from 40 to 50) in community settings. In hospital and institutional settings, the number of states allowing technicians to compound medications for dispensing increased by 33% (from 34 to 46); the number increased by 24% (from 34 to 43) in the community setting.

Competency Assessment. In May 2000, NABP resolved that it would (1) develop a national program to assess the competencies necessary for technicians to safely assist in the practice of pharmacy, (2) review existing technician certification programs to determine whether the development of its competence assessment program should be a cooperative effort with other groups, and (3) urge state boards to use this program as one criterion in determining the eligibility of technicians to assist in the practice of pharmacy.[92] NABP has now joined PTCB on the national certification program for pharmacy technicians and will work with state boards of pharmacy to encourage acceptance of the PTCB certification program as a recognized assessment tool for pharmacy technicians.[93] The use of the PTCB certification program will also be incorporated into NABP's *Model State Pharmacy Act and Model Rules*.

The Need for Regulation. The difficulties stemming from lack of regulatory oversight over pharmacy technicians go further than one might initially foresee. For example, if state regulations do not recognize a class of personnel (through registration or licensure), it is difficult to discipline such personnel in the event of misconduct. Several state boards have reported that the absence of such regulation is creating problems (Rouse MJ, personal communication, 2001 Oct and Nov). For example, in the absence of adequate controls, pharmacy technicians who have committed an act of misconduct, such as drug diversion, can move from site to site, or state to state, without being traced or being held accountable. NABP and many state executives and pharmacists have called for better systems of control and measures to track disciplinary actions. By 2000, at least 25 states had incorporated disciplinary procedures for technicians in their regulations.[92]

Among the regulatory issues that remain in flux, none is more important than defining the roles and responsibilities of supportive personnel and the titles they are assigned. Pharmacy supportive personnel perform a wide array of services. Some state regulations recognize this and have differentiated levels of supportive personnel; some states have specific requirements for technicians-in-training. Multiple levels of pharmacy supportive personnel may continue to be required in the future, and the levels may vary among and within practice settings. The profession needs to determine what these levels should be and to define the role and function, competencies, education, training, and level of supervision appropriate for each.

Time for Action

Pharmacy faces a serious work force shortage at a time when the public and health care providers alike are looking to pharmacists to assume expanded responsibility for better medication use. Better use of human resources is essential. When pharmacists limit their direct involvement in the technical aspects of dispensing, delegate this responsibility to pharmacy technicians working under their supervision, and increase the use of automated dispensing technology, they can fully concentrate on the services for which they are uniquely educated and trained. Only then will Dr. Tice's vision of the future become reality.

The utilization, education, training, and regulation of pharmacy technicians have changed dramatically in the past five years. National certification has played a particularly important role in these changes. Nonetheless, many challenges remain. Because these challenges are interrelated, resolving them requires a coordinated approach. The profession needs a shared vision for pharmacy technicians and other supportive personnel. This vision will provide the framework within which further necessary change can take place. Beginning with that much-needed vision, the major issues to be discussed and resolved might be expressed as follows:

1. *Vision*
   a. Define a vision for pharmacy technicians as an integral part of the vision and mission of the profession of pharmacy.
   b. Develop goals, objectives, and strategies to realize this vision, including determining who will lead the process and the specific roles, present and future, of all parties.
   c. Communicate the vision and goals to all stakeholders, including policymakers and the public.
2. *Roles, responsibilities, and competencies*
   a. Define the different levels of pharmacy supportive personnel and the responsibilities or functions appropriate for individuals at each level.
   b. Determine the competencies required for high-level performance at each level.
3. *Education and training*
   a. Establish standards (including eligibility criteria) for the education and training of each level of pharmacy supportive personnel.
   b. Establish requirements for maintenance of competence, where applicable, and create the systems to achieve this.
   c. Consider the cost implications of any new training model, and devise appropriate strategies to address cost concerns.
4. *Credentialing and accreditation*
   a. Develop or enhance appropriate credentials, in collaboration with PTCB and CCP, to reflect what is happening and required in practice.
   b. Determine what the most appropriate systems of accreditation for education and training programs for pharmacy technicians are and who should lead this process on behalf of the profession.
5. *Regulation*
   a. Determine the appropriate regulatory framework under which pharmacy technicians can optimally contribute to the achievement of pharmacy's mission.
   b. Work to bring about further changes in state pharmacy practice acts and regulations in order to achieve the desired regulatory framework.
   c. Work to bring about the development and adoption of standardized definitions and terminology for pharmacy supportive personnel.

Conclusion

Change does not come easily, and it is seldom embraced by everyone. As Kenneth Shine put it, when discussing the need for change in the health system: "The issue . . . will be whether these needed changes occur only begrudgingly as a reaction to external forces, or whether they occur proactively as a result of professional leadership."[94] The profession of pharmacy is changing in response to internal as well as external influences. Both pharmacists and pharmacy technicians are, therefore, part of an evolving partnership. Pharmacy must respond to the changes that are already taking place and be sufficiently creative and flexible to anticipate and accommodate future developments. The need to address the issues surrounding pharmacy technicians in a timely manner cannot be overemphasized. Proper preparation of pharmacy technicians to work with pharmacists is important in the promotion of public health and better use of medication. CCP, on behalf of its member organizations, offers this paper to provide a stimulus for professionwide action that can no longer wait.

References

1. Sonnedecker G, Kremers E. Kremers and Urdang's history of pharmacy. 4th ed. Madison, WI: American Institute of the History of Pharmacy; 1976:241.
2. American Society of Health-System Pharmacists. White paper on pharmacy technicians. *Am J Health-Syst Pharm.* 1996; 53:1793–6.
3. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer health system. Washington, DC: National Academy Press; 1999.
4. Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press; 2001.
5. Bureau of Health Professions. Report to Congress. The pharmacist workforce: a study of the supply and demand for pharmacists. Washington, DC: U.S. Department of Health and Human Services; 2000.
6. 1995 candidate handbook—national pharmacy technician certification examination. Washington, DC: Pharmacy Technician Certification Board; 1995:15.
7. American Society of Hospital Pharmacists. ASHP outcome competencies for institutional pharmacy technician training programs (with training guidelines). *Am J Hosp Pharm.* 1982; 39:317–20.
8. Bureau of Labor Statistics. Occupational outlook handbook. www.bls.gov/oco/ocos252.htm (accessed 2002 Apr 3).
9. Ervin KC, Skledar S, Hess MM, et al. Data analyst technician: an innovative role for the pharmacy technician. *Am J Health-Syst Pharm.* 2001; 58:1815–8.
10. Pharmacists, technicians, and technology: serving the patient. *Schering Report XXIII.* Kenilworth, NJ: Schering Laboratories; 2001.
11. Traynor K. Technician careers continue to evolve. *News/MD Society Health-Syst Pharm.* 2001; 24(4):1,4.
12. Accrediting Commission of Career Schools and Colleges of Technology directory. www.accsct.org/resource/resource_mainframe.html (accessed 2002 Apr 3).
13. 2001–2002 survey of pharmacy law. Park Ridge, IL: National Association of Boards of Pharmacy; 2001:34–44.
14. American Society of Hospital Pharmacists. Final report of the ASHP Task Force on Technical Personnel in Pharmacy. *Am J Hosp Pharm.* 1989; 46:1420–9.
15. American Society of Health-System Pharmacists. Chronology of ASHP activities for pharmacy technicians. www.ashp.org/technicians/chronology.html (accessed 2002 Mar 27).
16. Zellmer WA. Priorities for hospital pharmacy in the 1980s. *Am J Hosp Pharm.* 1980; 37:481. Editorial.
17. American Pharmaceutical Association. Report of the task force practitioner's and subprofessional's roles in pharmacy. *J Am Pharm Assoc.* 1969; 9:415–7.
18. Pharmacy Technician Certification Board: published and unpublished research, surveys, and employer consultations.
19. Ringold DJ, Santell JP, Schneider PJ. ASHP national survey of pharmacy practice in acute care settings: dispensing and administration. *Am J Health-Syst Pharm.* 2000; 57:1759–75.
20. Arthur Andersen LLP. Pharmacy activity cost and productivity study. www.nacds.org/user-assets/PDF_files/arthur_andersen. PDF (accessed 2002 Mar 27).
21. Muenzen PM, Greenberg S, Murer MM. PTCB task analysis identifies role of certified pharmacy technicians in pharmaceutical care. *J Am Pharm Assoc.* 1999; 39:857–64.
22. Model curriculum for pharmacy technician training. 2nd ed. Bethesda, MD: American Society of Health-System Pharmacists; 2001:iv,1.
23. Pew Health Professions Commission. Critical challenges: revitalizing the health professions for the twenty-first century. San Francisco: Center for Health Professions; 1995.
24. Gershon SK, Cultice JM, Knapp KK. How many pharmacists are in our future? The Bureau of Health Professions projects supply to 2020. *J Am Pharm Assoc.* 2000; 40:757–64.
25. National Association of Chain Drug Stores. Pharmacy: playing a growing role in America's health care. www.nacds.org/wmspage.cfm?parm1=378 (accessed 2001 Nov 29).
26. IMS HEALTH and NACDS Economics Department. Used with permission.
27. Kelly WN. Pharmacy contributions to adverse medication events. Conference report: understanding and preventing drug misadventures. www.ashp.com/public/proad/mederror/pkel.html (accessed 2002 Mar 27).
28. National Association of Chain Drug Stores, American Pharmaceutical Association, National Community Pharmacists Association. White paper. Implementing effective change in meeting the demands of community pharmacy practice in the United States; 1999.
29. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990; 47:533–43.
30. American Pharmaceutical Association Foundation. Project ImPACT.www.aphafoundation.org/Project_Impact/Impact.htm (accessed 2002 Mar 28).
31. Johnson JA, Bootman JL. Drug-related morbidity and mortality: a cost-of-illness model. *Arch Intern Med.* 1995; 155:1949–56.
32. Johnson JA, Bootman JL. Drug-related morbidity and mortality and the economic impact of pharmaceutical care. *Am J Health-Syst Pharm.* 1997; 54:554–8.
33. Bootman JL, Harrison DL, Cox E. The health care cost of drug-related morbidity and mortality in nursing facilities. *Arch Intern Med.* 1997; 157:2089–96.
34. Strand LM. Building a practice in pharmaceutical care: Hoechst Marion Roussell lecture. *Pharm J.* 1998; 260:874–6.
35. Strand LM. Pharmaceutical care: Liverpool John Moores University seminar. *Pharm J.* 1998; 260:877–8.
36. Pharmacy Technician Certification Board Web site. www.ptcb.org/ (accessed 2002 Mar 28).
37. Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc.* 2001; 41:192–9.
38. Lease D. Can you trust your pharmacist? http://speakout.com/activism/opinions/2850-1.html (accessed 2002 Mar 28).
39. Schuman D. When pharmacies make mistakes. www.news-sentinel.com (accessed 2002 Mar 28).

40. Levine J. Assistants' role in the spotlight: study finds mistakes by pharmacy technicians. http://my.webmd.com/content/article/1728.55198 (accessed 2002 Mar 28).
41. Stolberg SG. Death by prescription: the boom in medications brings rise in fatal risks. www.nytimes.com/library/national/science/060399sci-prescriptions.html (accessed 2002 Mar 28).
42. Hendren J. Pharmacy technicians dispense drugs: prescriptions often filled by lower paid technicians.www.capecodonline.com/cctimes/archives/2000/mar/7/prescriptionsoften7.htm (accessed 2002 Mar 28).
43. Dooley K. 'Support personnel' handle pills: few standards regulate important job. *Lexington Herald-Leader.* 2001; Oct 22:11.
44. Kalman MK, Witkowski DE, Ogawa GS. Increasing pharmacy productivity by expanding the role of pharmacy technicians. *Am J Hosp Pharm.* 1992; 49:84–9.
45. Woller TW, Stuart J, Vrabel R, et al. Checking of unit dose cassettes by pharmacy technicians at three Minnesota hospitals: pilot study. *Am J Hosp Pharm.* 1991; 48:1952–6.
46. Ness JE, Sullivan SD, Stergachis A. Accuracy of technicians and pharmacists in identifying dispensing errors. *Am J Hosp Pharm.* 1994; 51:354–7.
47. Cowley E, Baker KR. Liability for errors in expanded pharmacy practice: issues for technicians and pharmacists. *J Am Pharm Assoc.* 2000; 40(suppl 1):S56–7.
48. National Coordinating Council for Medication Error Reporting and Prevention. Recommendations for avoiding error-prone aspects of dispensing medications. www.nccmerp.org/rec_990319.htm (accessed 2002 Apr 1).
49. Ray MD. Training hospital pharmacy technicians. *Am J Hosp Pharm.* 1984; 41:2595. Editorial.
50. Reeder CE, Dickson M, Kozma CM, et al. ASHP national survey of pharmacy practice in acute care settings—1996. *Am J Health-Syst Pharm.* 1997; 54:653–69.
51. Keresztes J, Palmer M, Lang SM, et al., eds. National pharmacy technician conference: looking toward the future. *J Pharm Technol.* 2001; 17 (suppl):S1–26.
52. Sanford ME, Faccinetti NJ, Broadhead RS. Observational study of job satisfaction in hospital pharmacy technicians. *Am J Hosp Pharm.* 1984; 41:2599–606.
53. American Society of Hospital Pharmacists. ASHP long-range position statement on pharmacy manpower needs and residency training. *Am J Hosp Pharm.* 1980; 37:1220.
54. Eichelberger BM. College-based technician training programs: producing without planning? *Am J Hosp Pharm.* 1979; 36:992–3.
55. Schafermeyer KW, Hobson EH, eds. The community retail pharmacy technician training manual. 3rd ed. Alexandria, VA: National Association of Chain Drug Stores and National Community Pharmacists Association; 1999.
56. Marks SM, Hopkins WA Jr. Pharmacy technician certification: quick-study guide. 2nd ed. Washington, DC: American Pharmaceutical Association; 2000.
57. Posey LM. Complete review for the pharmacy technician. Washington, DC: American Pharmaceutical Association; 2001.
58. Hopkins WA Jr. Complete MATH review for the pharmacy technician. Washington, DC: American Pharmaceutical Association; 2001.
59. Manual for pharmacy technicians. 2nd ed. Bethesda, MD: American Society of Health-System Pharmacists; 1998.
60. Pharmacy technician certification review and practice exam. Bethesda, MD: American Society of Health-System Pharmacists; 1998.
61. American Society of Health-System Pharmacists Commission on Credentialing. Accreditation standard for pharmacy technician training programs. www.ashp.org/technicians/techstnd.pdf (accessed 2002 Apr 1).
62. The Pharmacy Technician Educators Council. PTEC recommended pharmacy technology program content. www.rxptec.org/rptpc.html (accessed 2002 Apr 1).
63. Rouse MJ. Analysis of 36 pharmacy technician programs, 36 barbering and styling programs, and 34 cosmetology and styling programs listed in the ACCSCT Directory; 2001 Nov.
64. Moscou K. Pharmacy technician educators' attitudes toward education and training requirements for pharmacy technicians. *J Pharm Technol.* 2000; 16:133–7.
65. Pharmacy Technician Certification Board. Third Annual Stakeholder Forum; Leesburg, VA: 2001 Jun 13–14. (*Proceedings not yet published.*)
66. American Society of Health-System Pharmacists. Model curriculum for pharmacy technician training. www.ashp.org/technicians/model_curriculum/ (accessed 2002 Apr 1).
67. Summary of the final report of the Scope of Pharmacy Practice Project. *Am J Hosp Pharm.* 1994; 51:2179–82.
68. Rouse MJ. Personal communication with Nimmo CM, model curriculum committee leader. 2001 Oct.
69. Technical personnel in pharmacy: directions for the profession in society. Proceedings of an invitational conference conducted by the University of Maryland Center on Drugs and Public Policy and sponsored by the ASHP Research and Education Foundation. *Am J Hosp Pharm.* 1989; 46:491–557.
70. American Pharmaceutical Association Policy statements.
71. Professional policies adopted at the 54th annual session of the ASHP House of Delegates. *Am J Health-Syst Pharm.* 2002; 59:1563–7.
72. Barrow W, Milburn G, eds. A critical dictionary of educational concepts. 2nd ed. New York, NY: Teachers College Press; 1970.
73. Council on Credentialing in Pharmacy. Guiding principles or pharmacy credentialing activities. www.pharmacycredentialing.org/ (accessed 2002 Apr 1).
74. Accrediting Commission of Career Schools and Colleges of Technology. Getting accredited. www.accsct.org/getting/get_mainframe.html (accessed 2002 Apr 1).
75. Rouse MJ. (Letters to Eaton CJ, Associate Executive Director, Accrediting Bureau of Health Education Schools, and Puckett G, Associate Executive Director, Council on Occupational Education.) 2001 Nov.
76. American Society of Health-System Pharmacists. ASHP-accredited pharmacy technician training program directory. www.ashp.org/directories/technician/index.cfm (accessed 2002 Apr 1).
77. American Society of Health-System Pharmacists Commission on Credentialing. ASHP regulations on accreditation of pharmacy technician training programs. www.ashp.org/technicians/techregs.pdf (accessed 2002 Apr 1).
78. American Society of Health-System Pharmacists. Pharmacy technicians. www.ashp.org/technicians/index.html (accessed 2002 Apr 1).

79. Pharmacist.com. Getting your license. www. pharmacist.com/articles/l_t_0001.cfm (accessed 2002 Apr 1).
80. Association of Specialized and Professional Accreditors. Member code of good practice. www.aspa-usa.org/ (accessed 2002 Apr 1).
81. Burkhart A. Pharmacy's challenging environment: technicians as part of the solution. Paper presented at APhA Annual Meeting. San Francisco, CA; 2001 Mar 19.
82. Nouri L. The utilization of certified pharmacy technicians with automation and technology. Paper presented at APhA Annual Meeting. Washington, DC; 2000 Mar 12.
83. Murer MM. Innovations for enhancing patient safety and new roles for certified pharmacy technicians. Paper presented at ASHP Midyear Clinical Meeting. New Orleans, LA; 2001 Dec 4.
84. 1996–1997 Survey of pharmacy law. Park Ridge, IL: National Association of Boards of Pharmacy; 1997:32–40.
85. The Model state pharmacy act and model rules. Park Ridge, IL: National Association of Boards of Pharmacy; 2001.
86. Gans JA, Manasse HR. Memorandum to executive directors of state boards of pharmacy, state pharmacists associations, and state health-system pharmacists societies. Bethesda, MD: 1997 Oct 20.
87. National Association of Chain Drug Stores. Issue brief. 2002 Apr.
88. National Association of Boards of Pharmacy. Report of the Task Force on Standardization of Technicians' Roles and Competencies. 2000 May 8.
89. Texas State Board of Pharmacy. Rule §291.29: exemption from pharmacy technician certification requirements. www.tsbp.state.tx.us/Pharmacytechs.htm (accessed 2002 Apr 2).
90. Utah Division of Occupational and Professional Licensing. Pharmacy Practice Act. www.dopl.utah.gov/licensing/statutes_and_rules/58-17a.pdf (accessed 2002 Apr).
91. National Association of Boards of Pharmacy. Report of the NABP Committee on Law Enforcement/Legislation. 2000 Jan.
92. Madigan M. Regulatory evolution of pharmacy technicians. Paper presented at PTEC Annual Meeting. Toronto, Canada; 2001 Jul 10.
93. Pharmacy Technician Certification Board. News release 02-001. www.ptcb.org (accessed 2002 Apr 2).
94. Shine KI. President's report to the members. www.iom.edu/iom/iomhome.nsf/pages/2000+iom+president+report (accessed 2002 Apr 2).

Appendix—Policy Statements of National Associations

The following statements are published with the permission of the respective organizations and were accurate as of March 2002, with the exception of (d), which was accurate as of June 2002.

(a) The American Association of Colleges of Pharmacy
(b) The American Association of Pharmacy Technicians
(c) The American Pharmaceutical Association
(d) The American Society of Health-System Pharmacists
(e) The National Association of Chain Drug Stores
(f) The National Community Pharmacists Association
(g) The National Pharmacy Technician Association
(h) The Pharmacy Technicians Educators Council

The American Association of Colleges of Pharmacy

www.aacp.org/Docs/AACPFuntions/AboutAACP/4308_CumulativePolicies,1980-2001.pdf

Policies On Supportive Personnel

- AACP supports inclusion in the professional pharmacy curriculum of didactic and experiential material related to the supervision and management of supportive personnel in pharmacy practices. *(Source: Professional Affairs Committee, 1990)*
- Training for technicians in pharmacy must be based on competencies derived from tasks that are deemed appropriate by the profession and currently performed by technical personnel. *(Source: Professional Affairs Committee, 1989)*
- Pharmacy schools should offer their assistance to supportive personnel training programs to assure that programs meet appropriate educational objectives. *(Source: Professional Affairs Committee, 1987)*
- Training for supportive personnel in pharmacy must be based on sound educational principles with clearly established competency objectives. *(Source: Professional Affairs Committee, 1987)*

The American Association of Pharmacy Technicians

www.pharmacytechnician.com/

Code of Ethics for Pharmacy Technicians

Preamble

Pharmacy Technicians are healthcare professionals who assist pharmacists in providing the best possible care for patients. The principles of this code, which apply to pharmacy technicians working in any and all settings, are based on the application and support of the moral obligations that guide the pharmacy profession in relationships with patients, healthcare professionals and society.

Principles

- A pharmacy technician's first consideration is to ensure the health and safety of the patient, and to use knowledge and skills to the best of his/her ability in serving patients.
- A pharmacy technician supports and promotes honesty and integrity in the profession, which includes a duty to observe the law, maintain the highest moral and ethical conduct at all times and uphold the ethical principles of the profession.
- A pharmacy technician assists and supports the pharmacists in the safe and efficacious and cost effective distribution of health services and healthcare resources.
- A pharmacy technician respects and values the abilities of pharmacists, colleagues and other healthcare professionals.
- A pharmacy technician maintains competency in his/her practice and continually enhances his/her professional knowledge and expertise.
- A pharmacy technician respects and supports the patient's individuality, dignity, and confidentiality.

- A pharmacy technician respects the confidentiality of a patient's records and discloses pertinent information only with proper authorization.
- A pharmacy technician never assists in dispensing, promoting or distribution of medication or medical devices that are not of good quality or do not meet the standards required by law.
- A pharmacy technician does not engage in any activity that will discredit the profession, and will expose, without fear or favor, illegal or unethical conduct of the profession.
- A pharmacy technician associates with and engages in the support of organizations, which promote the profession of pharmacy through the utilization and enhancement of pharmacy technicians.

The American Pharmaceutical Association

www.aphanet.org

2001 Automation and Technical Assistance

APhA supports the use of automation for prescription preparation and supports technical and personnel assistance for performing administrative duties and facilitating pharmacist's provision of pharmaceutical care.

1996 Control of Distribution System (Revised 2001)

The American Pharmaceutical Association supports the pharmacists' authority to control the distribution process and personnel involved and the responsibility for all completed medication orders regardless of practice setting.
(*J Am Pharm Assoc.* NS36:396. June 1996)

1996 Technician Licensure and Registration

1. APhA recognizes, for the purpose of these policies, the following definitions:
   (a) Licensure: The process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Within pharmacy, a pharmacist is licensed by a State Board of Pharmacy.
   (b) Registration: The process of making a list or being enrolled in an existing list.
2. APhA supports the role of the State Boards of Pharmacy in protecting the public in its interaction with the profession, including the Boards' oversight of pharmacy technicians, through their control of pharmacists and pharmacy licenses.
3. In States where the Board of Pharmacy chooses to exercise some direct oversight of technicians, APhA recommends a registration system.
4. APhA reaffirms its opposition to licensure of pharmacy technicians by statute or regulation.
   (*J Am Pharm Assoc.* NS36:396. June 1996)

1971 Sub-professionals: Functions, Standards and Supervision

The committee recommends that APhA endorse the use of properly supervised supportive personnel in pharmacy practice as a positive step toward improving the quality and quantity of pharmaceutical services provided by the profession.
(*J Am Pharm Assoc.* NS11:277. May 1971)

1966 Sub-professionals

The committee would be opposed to any assumption of the pharmacist's professional functions by sub-professionals or technicians. There is a need to determine exactly what these functions are and the relative position of the pharmacy intern. Under no circumstance should a sub-professional program in pharmacy create an individual such as the former "qualified assistant" still practicing in some states.
(*J Am Pharm Assoc.* NS6:332. June 1966)

The American Society of Health-System Pharmacists

www.ashp.org
See also www.ashp.org/public/hq/ (accessed 2002 Apr 4).
See also www.ashp.org/public/hq/policy/2001Policy Positions.pdf (accessed 2002 Apr 4).

[*Editor's note: ASHP policy positions 0224 and 0025 (below) have been superseded by ASHP policy positions 0322 and 0521, respectively, which are printed elsewhere in this book. ASHP policy positions are updated annually and can be accessed at ASHP's Web site at www.ashp.org/aboutashp/.*]

0224

Credentialing of Pharmacy Technicians

Source: Council on Legal and Public Affairs

To advocate and support registration of pharmacy technicians by state boards of pharmacy (registration is the process of making a list or being enrolled in an existing list; registration should be used to help safeguard the public by interstate and intrastate tracking of the technician work force and preventing individuals with documented problems from serving as pharmacy technicians); further,

To advocate and support mandatory certification of all current pharmacy technicians and new hires within one year of date of employment (certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association); further,

To advocate the adoption of uniform standards for the education and training of all pharmacy technicians to ensure competency; further,

To oppose state licensure of pharmacy technicians (licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon a finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected); further,

To advocate that licensed pharmacists should be held accountable for the quality of pharmacy services provided and the actions of pharmacy technicians under their charge.

0212

Pharmacy Technician Training

Source: Council on Educational Affairs

To support the goal that technicians entering the pharmacy work force have completed an accredited program of training; further,

To encourage expansion of accredited pharmacy technician training programs.

0211

Image of and Career Opportunities for Pharmacy Technicians

Source: Council on Educational Affairs

To promote the image of pharmacy technicians as valuable contributors to health care delivery; further,

To develop and disseminate information about career opportunities that enhance the recruitment and retention of qualified pharmacy technicians.

0209

Substance Abuse and Chemical Dependency

Source: Council on Educational Affairs

To collaborate with appropriate professional and academic organizations in fostering adequate education on substance abuse and chemical dependency at all levels of pharmacy education (i.e., schools of pharmacy, residency programs, and continuing-education providers); further,

To support federal, state, and local initiatives that promote pharmacy education on substance abuse and chemical dependency; further,

To advocate the incorporation of education on substance abuse and chemical dependency into the accreditation standards for Doctor of Pharmacy degree programs and pharmacy technician training programs.

0025

Opposition to Creation of "Pharmacist Assistant" Category of Licensed Pharmacy Personnel

Source: House of Delegates

To reaffirm the following statement in the "White Paper on Pharmacy Technicians" (April 1996) endorsed by ASHP and the American Pharmaceutical Association:

"Although there is a compelling need for pharmacists to expand the purview of their professional practice, there is also a need for pharmacists to maintain control over all aspects of drug product handling in the patient care arena, including dispensing and compounding. No other discipline is as well qualified to ensure public safety in this important aspect of health care."

Further,

To note that some interest groups in pharmacy have advocated for the creation of a new category of licensed personnel called "Pharmacist Assistant" that would have (a) less education and training than pharmacists and (b) independent legal authority to perform many of the functions that are currently restricted to licensed pharmacists; further,

To support the optimal use of well trained, certified pharmacy technicians under the supervision of licensed pharmacists; further,

To oppose the creation of a category of licensed personnel in pharmacy such as "Pharmacist Assistant" that would have legal authority to perform independently those professional pharmacy functions that are currently restricted to licensed pharmacists.

8610

Pharmacy Technicians

Source: Council on Legal and Public Affairs

To work toward the removal of legislative and regulatory barriers preventing pharmacists from delegating certain technical activities to other trained personnel.

This policy was reviewed in 1997 by the Council on Legal and Public Affairs and by the Board of Directors and was found to still be appropriate.

The National Association of Chain Drug Stores

www.nacds.org

Issue Brief—Pharmacy Technicians (Issued October 2001; updated April 2002)

The Issue

Registration, training and certification of pharmacy support personnel (pharmacy technicians) and maximizing the duties that such pharmacy technicians can perform.

Background

Allowing pharmacy technicians to be utilized to the fullest extent possible without any ratio will:

- Enhance pharmacists availability to counsel patients and to confer with other health professionals;
- Improve overall service to patients;
- Ease workload and improve professional satisfaction for pharmacists; and,
- Enhance efficiency and improve resources available for meeting the increased prescription volume and addressing the pharmacist shortages.

Certification of Pharmacy Technicians

- Certification should be voluntary and not mandatory.
- "Certification" exams should be effective tools for evaluating pharmacy technicians at the various pharmacy practice sites, such as community retail pharmacies, hospital pharmacies, and other practice settings.
- If pharmacy technicians decide to be certified they should be permitted to perform expanded duties and responsibilities.
- Pharmacy technicians, even if not certified, should be permitted to do routine nonjudgmental dispensing functions including, but not limited to, handling nonjudgmental third party and other payment issues, offering the patient the availability of the pharmacist for counseling, placing telephone calls to prescribers for refill requests, taking phone calls from prescribers' offices authorizing refill prescriptions, and preparing prescriptions for pharmacist's final review.

Pharmacy Technician Training and Examinations

- Boards of Pharmacy should allow for employer-based pharmacy technician training programs and examination pursuant to a Pharmacy Technician Training Manual.
- Boards of Pharmacy should recognize that employer-based technician training programs prepare technicians to work in their own particular practice setting, and that

technician training programs should be designed to teach competencies relevant to the particular practice setting.
- Chain pharmacy technician training programs and examinations should receive Board approval.

NACDS Position

- Continue to permit an unlimited number of technicians and allow each practice setting to determine their optimal ratio.
- Allow technicians to perform non-judgmental tasks ... those duties that do not require the expertise of a pharmacist.
- Allow technician training tailored to the pharmacy and to the company operations and standards.
- Allow certification to remain voluntary.
- Allow certified pharmacy technicians to perform additional duties and responsibilities commensurate with their competencies.
- Approve employer based training and examination pharmacy technician programs and recognize the importance of practice site specific training and examination programs such as community pharmacy based programs.
- Recognize the NACDS pharmacy technician training and examination program for certification of pharmacy technicians.

The National Community Pharmacists Association

www.ncpanet.org

NCPA supports the use of pharmacy technicians in community pharmacies to enhance the pharmacist's role in the provision of quality pharmacist care. NCPA believes the proper training and supervision of technicians by the pharmacist is critical to the health and safety of patients.

Technician Support and Technology:
Recognizing the current environment of regional shortages of pharmacists and the projected increase in prescription volume due to potential Medicare prescription drug benefit coverage and an aging population, NCPA recommends enhancing patient care and addressing manpower issues through the more efficient utilization of technician support and technology. NCPA strongly opposes the creation of any category of supportive personnel, which is not under the direct supervision of a licensed pharmacist.

The National Pharmacy Technician Association

www.pharmacytechnician.org/

Key Professional Issues
Medication Errors:
NPTA feels that the use of highly trained, educated and certified pharmacy technicians in the pharmacy profession will assist in efficiently and effectively reducing the occurrence of medication errors.

Technician Liability:
NPTA feels that with the emergence of national technician certification, producing increased roles and responsibilities, the issue of technician liability will become an evermore-present factor. Currently, NPTA does not have a position statement on technician liability.

Technician Education and Training:
NPTA fully supports formalized education and training programs at institutions of higher education. NPTA feels strongly that at some point, pharmacy technicians should be required to obtain a degree/certificate to be allowed to practice as a pharmacy technician. At this point, NPTA does not have a position statement on whether this degree should be a one or two year degree, when this policy should be implemented, or an appropriate approach for those already practicing. The requirement of formal education for pharmacy technicians, which is not present in most states, will be an integral part of the advancement of pharmacy practice, patient safety and a more efficient/effective healthcare system.

Technician Certification, Regulation and Credentialing
National Certification:
NPTA fully supports legislated requirements of certification by pharmacy technicians across the United States. National Certification is an appropriate and effective first step towards the educational and training goals for pharmacy technicians of the future.

Continuing Education:
NPTA strongly believes that an independent organization should be setup to accredit and monitor providers of pharmacy technician level continuing education programs. NPTA feels that while certified pharmacy technicians should be allowed to utilize ACPE CE Programs, that no organization (local, state or national) should make ACPE programs a requirement, since currently all ACPE programs are designed at the pharmacist's level.

The Pharmacy Technicians Educators Council

www.rxptec.org/

PTEC Recommendations and Goals
PTEC strongly recommends that all pharmacy education and programs seek ASHP accreditation.

PTEC strongly recommends that all pharmacy technician-training programs have a minimum of 600 contact hours, in accordance with ASHP accreditation standards.

In the short term, PTEC will:

- Work with AACP to design and implement programs which would provide step-wise technician training curriculum credits which could be used towards pharmacist training and education.
- Advocate a PTEC representative attend AACP board meetings, and invite AACP officers to attend PTEC board meetings.

PTEC advocates that:

- Within 5 years, all technician-training programs have a *minimum* of 600 contact hours; and
- Within 10 years, all technician-training programs evolve into 2-year associate degree programs.

PTEC recognizes the need for, and supports the development and introduction of, appropriate credentials for pharmacy technicians, including at the specialty level.

PTEC will work with AACP to design and implement programs which would provide step-wise technician-training curriculum credits that could be used towards pharmacist training and education.

The PTEC recommended pharmacy technology program content is published on its website: www.rxptec.org/rptpc.html

---

The following organizations have endorsed this document: Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy, American College of Apothecaries, American College of Clinical Pharmacy, American Council on Pharmaceutical Education, American Pharmaceutical Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, Board of Pharmaceutical Specialties, Commission for Certification in Geriatric Pharmacy, Pharmacy Technician Certification Board, and Pharmacy Technician Educators Council.

Development of this white paper was supported by an educational grant from PTCB.

The bibliographic citation for this document is as follows: American Society of Health-System Pharmacists. White paper on pharmacy technicians 2002: Needed changes can no longer wait. *Am J Health-Syst Pharm.* 2003; 60:37–51.

This document was also published in the *Journal of the American Pharmaceutical Association.*

ORIGINAL INVESTIGATION

Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units

Suzan N. Kucukarslan, PhD; Michael Peters, RPh, BCPS; Mark Mlynarek, RPh, BCPS; Daniel A. Nafziger, MD, MS

Background: Previous studies found that medication errors result from lack of sufficient information during the prescribing step. Therefore, it is proposed that having a pharmacist available when patients are evaluated during the rounding process may reduce the likelihood of preventable adverse drug events (ADEs). The objectives of this study were to evaluate the impact of having a pharmacist participate with a physician rounding team on preventable ADEs in general medicine units and to document pharmacist interventions made during the rounding process.

Methods: A single-blind, standard care–controlled study design was used to compare patients receiving care from a rounding team including a pharmacist with patients receiving standard care (no pharmacist on rounding team). Patients admitted to and discharged from the same general medicine unit were included in the study. The main outcome measure of this study was preventable ADEs. Patient records were randomly selected and evaluated by a blinded process involving independent senior pharmacist specialists and a senior staff physician. Interventions made by the pharmacists in the treatment group were documented.

Results: The rate of preventable ADEs was reduced by 78%, from 26.5 per 1000 hospital days to 5.7 per 1000 hospital days. There were 150 documented interventions recommended during the rounding process, 147 of which were accepted by the team. The most common interventions were (1) dosing-related changes and (2) recommendations to add a drug to therapy.

Conclusion: Pharmacist participation with the medical rounding team on a general medicine unit contributes to a significant reduction in preventable ADEs.

Arch Intern Med. 2003;163:2014-2018

From the Department of Pharmacy Services, Henry Ford Hospital, Detroit, Mich. Dr Nafziger is now with Goshen Health System, Goshen, Ind. The authors have no relevant financial interest in this article.

MEDICATION ERRORS occur more frequently than expected. Lazarou et al[1] stated that fatal adverse drug events (ADEs) were the sixth leading cause of death in the United Stated in 1994, with 10.9% of all hospital patients experiencing some adverse drug reaction and 2.1% of admissions resulting in serious events. A systems solution that looks at processes rather than at individual behavior is proposed as a viable approach to address the medication error problem.[2-4] When processes are examined, a common root cause of medication errors occurs at the time when decisions about therapy are made.[5,6] Failure to obtain sufficient information about the patient or about the pharmaceutical agent has contributed to medication errors. Thus, modifying the rounding process by adding the expertise of a pharmacist is proposed as a systems improvement to address the medication error problem.

Having a pharmacist on a rounding team in an intensive care unit (ICU) has been shown to reduce the incidence of ADEs by two thirds.[7] The rationale for putting a pharmacist in an ICU is that those patients are sicker and thus require a greater complexity of care. However, patients admitted to a non-ICU also have many comorbidities, which require careful pharmacological management. One would also expect a significant reduction in medication errors. Thus, we asked the following questions:

1. Is there a significant reduction in preventable ADEs for patients cared for by rounding teams with pharmacists?
2. What were the pharmacists interventions during the rounding process?
3. Is there a significant reduction in secondary outcome measures, such as length of stay and resolution of condition?

METHODS

The study was conducted at Henry Ford Hospital in Detroit, Mich, from September 5, 2000, through November 31, 2000. Patients admitted to and discharged from the general practice unit and the internal medicine service were included in the study.

SAMPLE

Henry Ford Hospital has 2 patient care units considered primarily internal medicine service. Both of these units were included in the study, one as the intervention group and the other as the control group. Patients had equal chance of being admitted to the control group or the intervention group. The admitting process was based on the availability of beds and physician service. Patients in both groups were included in the study if they were admitted to the internal medicine service and remained in the same patient care unit. The demographics and number of comorbidities in both groups were compared to determine if they were similar.

Two clinical pharmacists were assigned to provide patient care services at the bedside. Their services included rounding, documenting pharmacotherapy history, and providing discharge counseling. The pharmacist-patient ratio was approximately 1:15. Services were provided Monday through Friday, 7 AM to 3:30 PM. The control group received standard care. Standard care was provided by 1 pharmacist for approximately 30 patients. Pharmacists identified medication-related problems through the review of medication orders (ie, medication administration records) every morning. Also, a list of medications, which require evaluation because of cost or safety, was used to identify potential medication-related problems. Both processes are retrospective methods of evaluating medication profiles vs the prospective method of evaluating patients' medications when pharmacists round with physicians. The 2 practice models existed concurrently. Pharmacists for both the intervention and control groups have bachelor of science degrees in pharmacy, with number of years of experience ranging from 2 to 25 years. Pharmacists' competencies are maintained by annual departmental training and educational modules. There were 6 different pharmacists rotating through the study practice model.

PHARMACIST INTERVENTIONS

An intervention documentation form was developed for the pharmacists, based on the interventions identified by Leape et al.[7] The intervention types and response by the rounding team were documented. The interventions identified by Leape et al[7] were (1) clarification of drug order; (2) provision of drug information; (3) recommendation of alternative therapy; (4) identification of drug interaction; (5) identification of "systems error"; (6) identification of drug allergy; (7) approval of nonformulary use of a drug; (8) provision of special-order drug; and (9) identification of ADE.

PRIMARY OUTCOME MEASURE: PREVENTABLE ADEs

A preventable ADE was defined as an undesired reaction to medication, which may have been prevented by appropriate drug selection or management. Two senior pharmacist specialists who round in the critical care areas reviewed the emergency department notes, progress notes, nursing flow sheets, medication orders, medication administration records, and laboratory reports. The senior pharmacists (M.P. and M.M.) and coauthors were blinded to the patients' identity and patient care unit assignment. Each documented the preventable ADE (κ=0.87 for nonrandom agreement). The physician coinvestigator (D.A.N.) reviewed the patient documents for those patients with ADEs identified by the senior pharmacists (κ=0.71). The pharmacist and physician coinvestigators did not adjudicate any disagreements regarding the preventable ADEs. The physician evaluation was the final step to identify the preventable ADEs.

Table 1. Comparison of Patient Characteristics for Control Group vs Study Group

Characteristic	Study Group (n = 86)	Control Group (n = 79)	P Value
Age, mean (SD), y	53.94 (18.95)	56.49 (19.6)	.40
Comorbidities, mean (SD), No.	4.80 (2.16)	4.96 (2.04)	.63
Race, No. (%)			
African American	69 (80)	65 (82)	.51
White	17 (20)	13 (17)	
Other	0	1 (1)	
Sex, No. (%)			
Male	36 (42)	36 (46)	.63
Female	50 (58)	43 (54)	

SECONDARY OUTCOME MEASURES

Length of stay and time to respond to therapy were both evaluated in the study. We expected a shorter length of stay and time to respond to therapy for patient care units that include pharmacists in the rounding process. The length of stay is determined by the patient's recovery time, the efficiency of the discharge process, and the patient's discharge disposition. Therefore, we included time to respond to therapy as another outcome measure, which was expected to be a more direct measure of patient's response to therapy. This measure was also documented by the senior pharmacists, who reviewed the patient documents and determined the time to resolution of the condition. The progress notes were often used. For cases in which resolution was not an outcome (ie, terminally patients and chronic conditions), the time to resolution of the condition was considered missing data. The pharmacists reviewed cases individually and then together to reach consensus.

PATIENT VARIABLES

The study and control groups were compared using age, sex, race, number of comorbidities, and the number of medications ordered for the patient during the admission. The number of comorbidities were secondary or complicating conditions documented in the discharge summary prepared by the physician caring for the patient. The comorbidities were equally weighted when calculating the sum of comoribities for each patient.

STATISTICAL ANALYSIS

Patient variables for the control and study groups were compared using analysis of variance for age and number of comoribidities and χ^2 analysis for sex and race. The number of preventable ADEs were compared using χ^2 analysis. SPSS for Windows version 10.0 (SPSS Inc, Chicago, Ill) was used.

RESULTS

There were 165 patients in the study. Both the control and intervention groups were not significantly different with respect to age, sex, race, and number of comoribidities (**Table 1**).

The pharmacists provided 150 interventions during the rounding process for the patients in the study group. The physicians accepted 147 of the 150 recommendations made by the pharmacists. The most common intervention was recommending dosage or fre-

Table 2. Pharmacist Intervention Recommendations Made During Rounding Process (Study Group)

Intervention	No. of Recommendations (% of Total)*	No. Accepted by Physicians
Dosage or frequency	52 (35)	52
Addition of drug to therapy	31 (21)	30
Identification of potential problem with continuing therapy after discharge	12 (8)	11
Deletion of drug from therapy	11 (7)	11
Laboratory monitoring	9 (6)	9
Therapeutic alternative	8 (5)	8
Intravenous to oral conversion	7 (5)	6
Identification of adverse drug reaction	6 (4)	6
Approval of nonformulary or restricted drug	4 (3)	4
Clarification of order	4 (3)	4
Drug interaction	3 (2)	3
Preferred agent	2 (1)	2
Therapeutic duplication	1 (1)	1
Total	**150** (100)	**147**

*Percentages do not total 100 because of rounding.

Table 3. Preventable Adverse Drug Events

Medication-Related Metrics	Study Group (n = 86)	Control Group (n = 79)	*P* Value
Total patient days	350	339	NA
No. of medications per patient, mean (SD)	15.58 (5.73)	14.95 (7.67)	.55
Total drug charges, $	32 647	30 450	NA
No. of events (%)	2 (2.5)	9 (10)	.02
No. of events per 1000 patient days	5.7	26.5	NA
No. of events per $1000 drug charges	0.06	0.60	NA

Abbreviation: NA, not applicable.

quency for medication followed by the addition of medication. Pharmacists also made recommendations for discharge medication that would reduce the potential for problems after discharge. One problem addressed by the pharmacists was the affordability of medication. Approximately 1 of 10 of the patients were cash customers. Therefore, recommending affordable medication for these patients should reduce the likelihood of noncompliance due to economic reasons (**Table 2**).

Preventable ADEs were compared with the rates determined by Leape et al.[7] The control group (phase 2) for the ICU patients in the study by Leape et al had a rate of preventable ADEs of 12.4 per 1000 patient days. The control group in the internal medicine unit for the present study was 26.5 per 1000 patient days. Leape et al found the rate for preventable ADEs for the study group to be 3.5 per 1000 patient days (phase 2). In the present study, the internal medicine group with the rounding pharmacist had a rate of 5.7 preventable ADEs per 1000 patient days. The reduction in preventable ADEs was 72% in the study by Leape et al and 78% in the present study. A similar reduction is found in the ratio of preventable ADEs per $1000 drug charges in the present internal medicine unit study (**Table 3**).

The preventable ADEs listed in **Table 4** serve to illustrate how these could have been avoided with the inclusion of a pharmacist on the rounding team. Contraindications, dosing recommendations, and appropriate selection of antihypertensives account for all of the documented cases. Pharmacists working in a central dispensing area are less able to assist the physician with prescribing information. Also, the standard care model, in which the pharmacist is available on an as-needed basis to answer questions or to resolve problems after the prescribing decisions have been made, may not be sufficient to reduce preventable ADEs.

We compared the length of stay of patients with a preventable ADE. Patients with an ADE had on average a 1.4-day longer stay at the hospital.

When comparing the study and the control group with respect to the secondary outcome measures, the study group had on average a 0.3-day shorter stay and shorter time to resolution of the condition. However, these figures were not significantly different from the control group. The readmission rate was 44% less for the study group; however, the difference was not significant. The drug charges were very similar. Our study showed that 21% of the pharmacist's recommendations identified a situation in which the addition of a drug to the patient treatment plan was indicated. This finding raises the question of whether drug charges should be the performance measure for pharmacy departments. Pharmacists should also be accountable for assuring appropriate use of pharmaceuticals.

COMMENT

The principal cause of medication errors is insufficient information when the prescribing decisions are made.[5] The prescribing decisions in teaching institutions are often made during the rounding process. Previous research has identified that adding a pharmacist to the rounding team in the ICU reduces preventable ADEs by 72%.[7] Our study shows a pharmacist on the rounding team in the general medicine unit reduces preventable ADEs by 78%. The interventions made by pharmacists in this study included dosage or frequency adjustments (35%), the addition of drugs to therapy (21%), the identification of potential problems with continuing therapy after discharge (8%), deletion of drugs from therapy (7%), and recommendation of laboratory monitoring (6%).

A system is defined as "any collection of components and the relationships between them, whether the components are human or not, when components have been brought together for a well-defined goal or purpose."[8] Current health care delivery systems are responsible for sicker patients in an environment that is challenged with limited resources. A systems approach to care can reduce the waste attributed to error by including specialized components in the process. Pharmacists specialize in pharmacotherapy and can assist physicians in making prescribing decisions. The rounding process involves a compilation of information to diagnose the

Table 4. Description of Preventable Adverse Drug Events (ADEs)

Medication	Description of Problem	Recommendation to Prevent ADE
Narcotics	Exacerbate delirium; patient complaint of abdominal pain and broken bones in chest	Recommend benzodiazepine therapy
Narcotics	Exacerbate gastroparesis	Add stool softener to treatment regimen
Furosemide, lisinopril, and oral potassium	Hyperkalemia	Discontinue oral potassium therapy
Multiple antihypertensives: IV furosemide, hydrochlorothiazide, lisinopril, ACE inhibitor, calcium channel blocker, and metoprolol tartrate	Hypotension	Recommend multiple antihypertensive medications; amlodipine besylate and hydrochlorothiazide therapies should be discontinued (do not benefit patient and increase risk of hypotension)
Metoprolol tartrate twice daily, clonidine patch	Bradycardia	Discontinue medications; monitor blood pressure
Aggressive increase in labetolol hydrochloride dosage to 800 mg 3 times per day, hydralazine hydrochloride, and sodium nitroprusside	Hypotension	Dosage of labetolol hydrochloride was increased to 800 mg every 8 h within short time; recommend 400 mg twice a day and maintaining hydralazine dosage
Order written for ibuprofen, 600 mg every 8 h, to be given as scheduled medication plus 600 mg every 8 h as needed	Gastritis	Recommend acetaminophen therapy to control pain
Warfarin sodium, 5 mg nightly	Baseline INR of 2.10; 2 d after start of warfarin use, INR increased to 7.4	Monitor INR daily
Ampicillin sodium–sulbactam sodium, 3 g every 6 h; patient has serum creatinine level of 2.2 mg/dL (195.5 μmol/L) (borderline acute renal failure)	Diarrhea	Recommend reducing ampicillin sodium–sulbactam sodium dosage to 3.0 g every 12 h
Bisacodyl, 10 mg by rectum twice daily around the clock	Diarrhea	Recommend bisacodyl therapy, 10 mg twice daily as needed, or stool softener twice daily
Atenolol, 75 mg/d	Bradycardia	Maximum recommended daily dose of atenolol, 50 mg (estimated creatinine clearance, 33 mL/min [0.55 mL/s], and has hydronephrosis secondary to carcinoma)

Abbreviations: ACE, angiotensin-converting enzyme; INR, international normalized ratio; IV, intravenous.

medical problem and to develop a treatment plan. This is the step in the patient care process in which the pharmacist may contribute to improving the quality of patient care. In most practice settings, the pharmacist is placed distant from the medication selection step of the patient care process. The information required for evaluating the appropriateness of drug therapy is limited for most pharmacists practicing in an institutional setting. Intervening with recommendations to adjust doses, to add or delete drugs to therapy, to monitor laboratory values, or to identify potential problems at discharge are more difficult to identify and to respond to in a timely manner because of the pharmacist's distance from the decision-making process.

The Institute of Medicine report *To Err Is Human* recommends a systems approach to addressing the prevalence of medical error.[3(p158)] The Institute of Medicine states that pharmacists should be included during the rounding process as one strategy to improve medication safety.[3(p158)] Thus, the pharmacist would be able to recommend medication, doses, and monitoring parameters for the patient. Recommendations are more effective during the rounding process when these decisions are made. A survey of 934 acute care hospitals in 1992 found that 14.9% of them had pharmacists participating in the rounding process. Those hospitals that did have this service had significantly less drug charges.[9] Our study shows that significant savings can be achieved by reducing preventable ADEs. We found that patients with preventable ADEs had lengths of stay 1.4 days longer than those who did not have an unexpected event. This is consistent with the findings published by Senst et al[6] in 2001. If we consider the cost of a semiprivate room and the internal medicine service charges only, this is an extra $923 per admission.

There are limitations to our study. First, there are no baseline data for both the study and the control groups as in the study by Leape et al.[7] Therefore, we cannot control for any changes in the standard of care over time. However, there should be very limited change in practice over the short period (3 months) of the study. Also, the impact of any changes in the standard of care or hospital policy should be the same for both the control and study groups.

Second, we did not use a randomized study design. Randomization was not possible, since it would have been disruptive to the admitting process of the institution. Therefore, we chose to identify patient factors that may bias the results. We compared the groups with respect to patient age, sex, race, comorbidities, and the number of medications. We found no significant differences between the groups. However, this does not protect the results from any other potential biases that would have been controlled for by randomizing.

Third, the study was limited to patients admitted to the general medicine unit. The results cannot be generalized to other specialty units such as cardiology or nephrology. Further research is required to evaluate the impact of rounding pharmacists on preventable ADEs in specialty units.

Finally, the preventable ADE rate in the study by Leape et al[7] was lower than the reported rate in our study, even though the study by Leape et al involved intensive care patients. We used the same definition of preventable ADE. However, there could have been differences in how these definitions were operationalized. Also, it may have been less clear in the ICU population if the drug caused a reaction or if the patient condition deteriorated, thus contributing to the differences in measuring preventable ADEs. However, the percentages of reduction in preventable ADEs with a pharmacist on the rounding team in our study and the study by Leape et al[7] were consistent.

In summary, a physician rounding team with a pharmacist contributes to a significantly lower likelihood of preventable ADEs than a rounding team without a pharmacist. This was demonstrated in ICUs by Leape et al[7] and in general medicine units in our study.

Accepted for publication November 14, 2002.

This study would not have been possible without the assistance of Ed Szandzik, RPh, MBA, David B. Wright, PharmD, Mark Touchette, PharmD, Kate M. Truong, PharmD, Christopher Zimmerman, PharmD, and Theresa Mazurek, RPh, who supported the pharmacist-counseling model. We express gratitude for their support and vision.

Corresponding author and reprints: Suzan N. Kucukarslan, PhD, Henry Ford Hospital, Department of Pharmacy Services (ECFP-BS), 2799 W Grand Blvd, Detroit, MI 48202 (e-mail: skucuka1@hfhs.org).

REFERENCES

1. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA.* 1998;279:1200-1205.
2. Leape LL. Error in medicine. *JAMA.* 1994;272:1851-1857.
3. Institute of Medicine. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 1999.
4. Bates DW, Miller EB, Cullen DJ, et al. Patient risk factors for adverse drug events in hospitalized patients. *Arch Intern Med.* 1999;159:2553-2560.
5. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events implications for prevention. *JAMA.* 1995;274:29-34.
6. Senst BL, Achusim LE, Genest RP, et al. Practical approach to determining costs and frequency of adverse events in a health care network. *Am J Health Syst Pharm.* 2001;58:1126-1132.
7. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999;282:267-270.
8. Moray N. Error reduction as a systems problem. In: Bogner MS, ed. *Human Error in Medicine.* Hillsdale, NJ: Erlbaum; 1994.
9. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacist staffing and drug costs in United States hospitals. *Pharmacotherapy.* 1999;19:1354-1362.